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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06

A1

(11) International Publication Number: WO 96/32078

(43) International Publication Date: 17 October 1996 (17.10.96)

(21) International Application Number: PCT/IB96/00146

(22) International Filing Date: 26 February 1996 (26.02.96)

(30) Priority Data:
08/421,960 14 April 1995 (14.04.95) US

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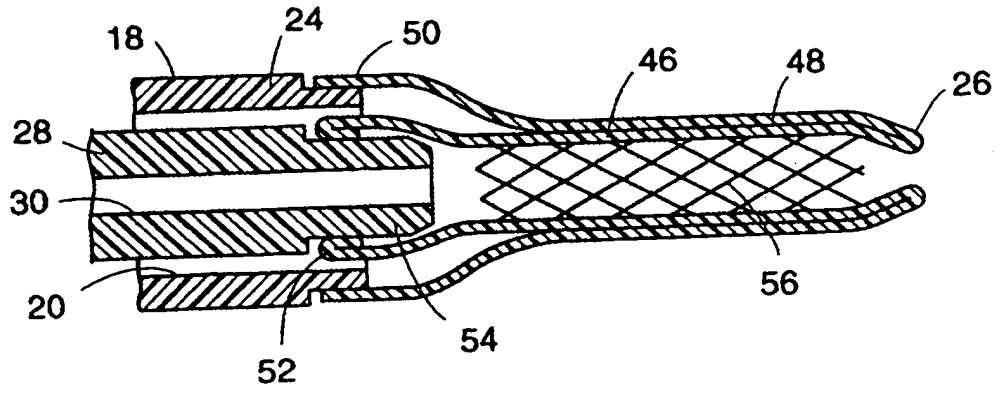
(81) Designated States: AU, CA, DE (Utility model), JP, MX, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: ROLLING MEMBRANE STENT DELIVERY DEVICE



(57) Abstract

A device for deploying radially self-expanded stents and other radially expandable stents includes an inner catheter (28, 82, 130, 142), an outer catheter (18, 88, 132, 146) surrounding the inner catheter, and a tubular stent retaining sheath (22, 92, 118, 150) formed of a rolling membrane. The sheath is doubled over upon itself to provide an inner sheath layer (46, 104, 120, 156) attached to the inner catheter, and an outer sheath layer (48, 108, 122, 162) attached to the outer catheter. The sheath layers extend along and surround a radially self-expanding stent (56, 102, 124, 160), to maintain the stent distally of the inner catheter and in a radially compressed, axially elongated state. Distally of the stent, the inner and outer sheath layers converge and are narrowed in the distal direction to define a tapered distal tip (26, 106, 128, 164). To release the stent, the outer catheter is moved proximally to roll the membrane away from its surrounding relation to the stent, whereupon the stent radially self-expands progressively, beginning at its distal end. When completely retracted after stent release, the sheath surrounds a distal region of the inner catheter, and can provide a protective layer between arterial tissue and a dilatation balloon (58, 110, 148) supported along the distal region. As an alternative, a stent formed of a recovery metal can be plastically deformed into a reduced radius state for delivery, which facilitates use of a more flexible stent retaining sheath. A further alternative involves securing the sheath proximally of the dilatation balloon, so that sheath retraction leaves the dilatation balloon exposed, rather than covered by the sheath.

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ROLLING MEMBRANE STENT DELIVERY DEVICE

BACKGROUND OF THE INVENTION

The present invention relates to devices for deploying body implantable prosthesis intended for fixation in body lumens, and more particularly to the delivery and placement of radially self-expanding stents or other radially expandable stents.

Certain prosthesis known as radially self-expanding stents are useful in a variety of patient treatment and diagnostic procedures, for fixation in blood vessels, biliary ducts and other lumens to maintain the passages. A highly preferred construction for a radially self-expanding stent is a flexible tubular braided structure formed of helically wound thread elements, as disclosed in U.S. Patent No. 4,655,771 (Wallsten). Wallsten teaches use of a catheter for delivering the stent to the intended treatment site. A pair of grips maintain the stent at the distal end of the catheter and are controlled by an operational member at the proximal end of the catheter to release the stent after positioning and initial medial stent self-expansion.

Another approach to deploying self-expanding stents is shown in U.S. Patent No. 4,732,152 (Wallsten et al) and in U.S. Patent No. 4,848,343 (Wallsten et al). Often referred to as the "rolling membrane" method, this approach utilizes a tubular membrane folded over upon itself to provide a double wall for maintaining a self-expanding stent at the distal end of the catheter. The outer wall of the membrane is movable proximally to expose the stent and allow a radial self-expansion, beginning at the distal end of the stent. More particularly, one end of the membrane is attached to an inner catheter or probe, and the other end of the membrane is connected to an outer catheter that surrounds the probe. When the outer catheter is moved proximally relative to the inner catheter, it moves the outer wall of the membrane proximally as well, to expose the stent and allow radial self-expansion.

Yet another approach is shown in PCT patent application, Publication No. WO 94/15549 entitled "Method for Deploying Body Implantable Stent". This application describes several stent deployment devices employing interior and exterior catheters to deploy prostheses including radially self-expanding stents. One of these versions (Figures 9-13) employs a rolling membrane controlled through manipulation of the catheters to release a stent for self-expansion.

Stents constructed of a recovery metal, e.g. an alloy of titanium and nickel such as that sold under the brand name Nitenol, can be used in lieu of radially self-

expanding stents for certain applications. A recovery metal stent may be formed initially in an expanded radius configuration, then plastically deformed while cool into a reduced radius configuration for delivery to a treatment site. Following delivery the stent is heated, which causes it to radially expand toward its original radius and into contact with tissue at the treatment site. Devices for delivering recovery metal stents and radially self-expanding stents can be constructed according to the same general principles.

While quite effective in certain applications, these devices generally incorporate interior catheters, probes or other members surrounded by the stent being deployed, and generally rely on a relatively rigid outer member, usually an exterior catheter, to surround and maintain the stent under radial compression. Such devices may be too large for deploying stents within narrower blood vessels and other body passages, and may be difficult to maneuver distally through serpentine passages defined by the body lumens.

Frequently during a procedure involving stent deployment, it is desired to force the stent against surrounding tissue after its deployment. This insures a more secure positioning of the stent, a more uniform lumen for fluid flow, and also more reliably establishes a final axial length (i.e. degree of axial contraction) of the stent. It is important during lesion treatment procedures to determine the final length (or degree of axial contraction) of the stent after self-expansion, to insure that a given stent is of sufficient length in relation to the lesion being treated. A dilatation balloon, mounted near the distal end of the catheter, can be used for this purpose. When using such a balloon, it would be desirable to provide protection against accidental bursting of the balloon either during or after its inflation.

Therefore, it is an object of the present invention to provide a device for deploying radially self-expanding stents, with sufficient axial rigidity yet enhanced flexibility for accommodating advancement through narrow and non-linear body passages.

Another object is to provide a reduced diameter stent retaining tip for a stent deployment catheter.

A further object is to provide a stent delivery apparatus that affords good axial stiffness and tracking characteristics, whether steered through body passages or advanced over a guidewire.

Yet another object is to provide a device for delivering a radially self-expanding stent with a dilatation balloon expandable against the delivered stent to force it against surrounding tissue, and further incorporating a fluid tight membrane surrounding the dilatation balloon to afford added protection during high pressure dilatation procedures.

SUMMARY OF THE INVENTION

To achieve these and other objects, there is provided a device for deploying an expandable stent at a treatment site within a body. The device includes a first (or inner) catheter and a stent retaining member. The member is disposed at the distal end region of first catheter and includes an inner layer extending distally beyond the first catheter. The member is turned back upon itself to form an outer layer extended toward the first catheter. The inner layer is adapted to retain an expandable stent in a reduced state along its axial length, with the stent located distally of the first catheter. A means is operable to displace the outer layer relative to the first catheter after delivery, to remove the member from its retaining relation to the stent, to release the stent for expansion at the treatment site.

Preferably the retaining member is a sheath or rolling membrane that surrounds the stent to retain the stent in the reduced state. The preferred sheath comprises a tubular rolling membrane. Because the stent is maintained distally of the catheter rather than surrounding the catheter, it can be delivered at a diameter less than that of the catheter. The inner layer preferably has an inside diameter no larger than the outside diameter of the first catheter. When the stent is radially self-expanding, the inner layer alone (or a combination of the inner and outer layers) retains the stent in a radially compressed, axially elongated state.

The compressed stent and sheath cooperate with one another to provide an improved distal tip for the catheter. In addition to the reduced diameter, the compressed stent and membrane provide a highly favorable combination of axial rigidity and compliance of the tip in bending to accommodate tortuous passageways in blood vessels and other body lumens.

Further improvement is realized by shaping the sheath to form a tapered distal tip. This is accomplished by forming the sheath so that the inner and outer layers, near the point at which the sheath is turned back upon itself, converge in the

distal direction. If desired, axial filaments or other stiffening can be provided along the sheath.

Release of the stent involves retracting the sheath, i.e. moving the outer sheath layer proximally to progressively peel or roll the sheath membrane away from the stent. Preferably this is accomplished with a second or outer catheter that surrounds the first catheter and is attached at its distal end to the sheath outer layer. The sheath is rolled by moving the outer catheter proximally relative to the first (inner) catheter. Release is enhanced by a fluid tight construction of the membrane that facilitates introduction of a fluid under pressure between the inner and outer layers. Alternatively, selection of low friction membrane material, or application of low friction coatings to the membrane between the inner and outer sheath layers, can allow the rolling membrane to be withdrawn without applying pressure between the layers.

According to another aspect of the invention, a dilatation balloon is provided near the distal tip of the catheter. The sheath has sufficient length in its inner and outer layers combined, to exceed the axial distance from the catheter distal tip to a proximal end of the dilatation balloon. Consequently, the sheath after retraction extends proximally along the catheter from the distal tip, in surrounding relation to the balloon along the full length of the balloon. So arranged, the sheath provides a layer of protection particularly useful during high pressure angioplasty procedures. Were the dilatation balloon to burst, the dilatation fluid would tend to flow proximally along the sheath and catheter and remain inside of the sheath. Thus, the sheath protects arterial or other tissue against the risk of exposure to exploding or jetting balloon dilatation fluid. The sheath also prevents any resultant fragments of balloon material from escaping into the bloodstream.

A highly preferred device employs an exterior catheter with a lumen containing an interior catheter, with opposite ends of the sheath secured to the respective catheters and with the sheath inner and outer layers extending distally of both catheters. The outer catheter provides a reliable means for proximally pulling the outer sheath layer to release the stent. Fluids can be provided to the region between the sheath layers via a lumen of the exterior catheter. The sheath alone retains the stent, for a smaller diameter and more maneuverable yet axially rigid deployment device. When the sheath is retracted or proximally withdrawn, the distal

end of the inner catheter becomes the distal tip of the device. The sheath overlies and surrounds a dilatation balloon to protect tissue from exposure to jetting balloon dilatation fluid in the event of a balloon rupture during an angioplasty procedure.

IN THE DRAWINGS

For a further appreciation of the above and other advantages, reference is made to the following detailed description and to the drawings, in which:

Figure 1 is an elevation of a device for delivering and deploying a radially self-expanding stent in accordance with the present invention;

Figures 2 and 3 are enlarged sectional views of portions of Figure 1;

Figure 4 is a sectional view taken along the line 4-4 in Figure 1;

Figure 5 is a further enlarged view of the device distal end;

Figures 6-9 are schematic views illustrating use of the device to deploy a radially self-expanding stent;

Figure 10 is an elevation in section of a distal end region of an alternative embodiment device for deploying radially self-expanding stents;

Figure 11 is an elevational view of a distal region of another alternative embodiment deployment device;

Figure 12 is a sectional view taken along the line 12-12 in Figure 11; and

Figures 13 and 14 illustrate the distal end portion of a further alternative embodiment device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to the drawings, there is shown in Figure 1 a deployment device 16 for delivering a prosthesis, in particular a radially self-expanding stent, to an intended treatment location within a body lumen such as an artery. After delivering the stent, deployment device 16 is manipulated to controllably release the stent for radial self-expansion to a fixation site within the lumen. Following deployment, a balloon mounted on the device is expanded to force the stent radially outward against surrounding tissue, to more reliably establish a final stent position and axial length.

Deployment device 16 includes an elongate and flexible outer catheter 18 constructed of a biocompatible thermoplastic elastomer, e.g. polyurethane or nylon. The outside diameter of the catheter typically is in the range of 2-42 Fr. (0.7-14 mm). The preferred catheter diameter depends largely on the intended use. For example,

the preferred range for coronary applications is about 2-7 Fr. (0.7-2.3 mm), with peripheral applications calling for diameters of about 2-12 Fr. (0.7-4 mm). For abdominal aortic aneurysm, esophageal and tracheal applications, a more preferred range is 7-42 Fr. (2.3-14 mm). Outer catheter 18 has a lumen 20 that runs the length of the catheter.

A tubular sheath 22 is mounted to the distal end 24 of catheter 18. Sheath 22 extends distally beyond the catheter and is shaped to provide a distally converging tip 26. A portion of the outer catheter is broken away to reveal an elongate and flexible inner catheter 28 contained within lumen 20. The inner catheter can be constructed of similar materials employed to form the outer catheter. Inner catheter 28 has a lumen 30 running the catheter length, for containing a guidewire 32, shown to extend distally beyond tip 26.

At its proximal end, outer catheter 18 is mounted to a valve 34. The valve includes a port 36 for receiving fluids supplied via an extension tube 38. Such fluids proceed through the valve to lumen 30, then to the region about tip 26. A portion of valve 34 is removed to reveal an internal sealing gasket 40 that supports an elongate stainless steel tube 42 to guide axial movement of the valve. The stainless steel tube extends distally of the valve into lumen 20 of the outer catheter, and its distal end is joined to the proximal region of inner catheter 28. The stainless steel tube can extend from 10 mm to 200 mm distally along lumen 20, advantageously increasing the axial rigidity of device 16. Steel tube 42 can be perforated or formed as a coil near the distal end of the catheter to enhance its bending flexibility.

Catheters 18 and 28 can be moved axially relative to one another by hand manipulation to move valve 34 relative to steel tube 42. A hub 44 is bonded at the proximal end of stainless steel tube 42. For example, moving the valve proximally while maintaining the steel tube fixed retracts the outer catheter, i.e. moves catheter 18 in the proximal axial direction relative to inner catheter 28.

Sheath 22, often referred to as a rolling membrane, is pliable and flexible, and constructed of a suitable body compatible thermoplastic elastomer such as polyurethane. Polyethylene, nylon and their copolymers also may be employed. As best seen in Figure 2, sheath 22 is doubled over upon itself to form an inner sheath layer 46 and an adjacent outer layer 48, both of which are tubular. Sheath 22 is formed so that both layers 46 and 48 converge in the distal axial direction along tip

26. A proximal end 50 of the outer layer is mounted to the distal end 24 of outer catheter 18, in an annular, fluid tight joint. An opposite end of the sheath, i.e. a proximal end 52 of the inner layer, is attached in similar fashion to the distal end 54 of inner catheter 28. Along most of its length, sheath 22 extends axially such that its wall, in particular inner layer 46, defines an extension of guidewire lumen 30. At the distal tip is an opening of reduced size, yet sufficient to admit guidewire 32 and provide a transition zone from the guidewire to the constrained stent.

A radially self-expanding stent 56 is contained by sheath 22, entirely distally of inner catheter 28. Stent 56 has an open mesh or weave construction, formed of helically wound and braided filaments or perforated tubing of a resilient material, e.g. a body compatible metal such as stainless steel or a titanium nickel alloy. The stent also can be formed of a resilient polymer such as polypropylene or polyethylene. As shown in Figure 2, stent 56 is elastically deformed into a delivery configuration that reduces its radius and increases its axial length as compared to its normal shape when not subject to external stress. Inner and outer layers 46 and 48 surround the stent and cooperate to maintain it in the delivery configuration.

When stent 56 is radially compressed as shown, its elastic restoring force is applied radially against sheath layers 46 and 48. These sheath layers expand in response to the force of stent 56, until a restoring force in the layers counterbalances the stent restoring force. Sheath expansion is preferably virtually negligible.

As an alternative, the stent can be formed of a recovery metal, such as the nickel titanium alloy sold under the brand name Nitenol. Such stent is plastically deformable, so long as it remains sufficiently cool, into a reduced radius delivery configuration. While cool (e.g. at or below ambient temperature), the stent tends to remain in the reduced radius state. Consequently the surrounding sheath can have greater elasticity if desired, since the sheath need not counteract an elastic restoring force of the stent.

When the recovery metal stent is delivered and positioned at the treatment site, it is heated, which causes the stent to radially expand toward its original, larger radius state, and into intimate contact with tissue at the treatment site once the surrounding sheath has been retracted.

Sheath 22 is retractable by moving outer layer 48 proximally relative to inner layer 46. A hydrophilic material, e.g. polyvinyl pryoladone, is applied to sheath 22 along the outer surface of inner layer 46 and the inner surface of outer layer 48. Silicone or other lubricants also may be used. A liquid lubricant and priming fluid can be provided between the sheath layers, via lumen 20. The coating and lubricant facilitate sliding of the inner and outer layers relative to one another during retraction.

As best seen in Figure 5, sheath 22 is specially shaped in the region of the distal tip. More particularly, a distal region 66 of the outer layer and a distal region 68 of the inner layer are tapered to converge in the distal direction. Thus, not only does the tip profile converge; its thickness, as well, diminishes in the distal direction. Regions 66 and 68 further provide a transition region over which sheath 22 is treated to substantially alter its hardness. More particularly, sheath 22 and constrained stent 56 over the majority of their length are relatively rigid. Over the transition region, hardness diminishes steadily and considerably to a soft distal end of the tip. More particularly, the durometer of the distal end (Shore Hardness Test) is within a range of 20D-55D, and more preferably is about 90A. Further, an annular feature 70 is formed into the sheath along inner layer 46, to provide a better transition from the relatively rigid stent constraining region to the soft distal end.

A micropore 69 is formed through outer layer 48 to allow egress of liquids from between sheath layers 46 and 48. If desired, the micropore diameter can be selected for maintaining liquids between the sheath layers at a predetermined pressure. A typical diameter for micropore 69 is about 0.001 inches (0.0254 mm). Depending on the application, the micropore diameter may range from about 0.0005 to 0.12 inches (0.0127-3 mm).

With sheath 22 in the stent retaining state as shown in Figure 2, the distal region along the stent can conform to serpentine arterial passages as device 16 is advanced over guidewire 32 to the intended treatment site. The soft tip and transition regions 66 and 68 reduce the risk of damage to arterial walls or other tissue as the device is advanced.

Proximally of distal end 54 (Figure 3), a dilatation balloon 58 is secured to the inner catheter in fluid tight fashion at a proximal neck 60 and a distal neck 62. A balloon inflation lumen 64 is formed in the inner catheter, and is open to the interior

of balloon 58, whereby a balloon inflation fluid can be provided under pressure to radially expand balloon 58. Radiopaque markers 65 and 67 can be used to fluoroscopically indicate the balloon location.

In using device 16 to position and fix stent 56, the initial step is to position guidewire 32 within the patient's body using a guide cannula (not illustrated). This leaves guidewire 32 in place along an artery or other lumen, with a proximal portion of the guidewire outside of the patient. Deployment device 16 is advanced over the guidewire beginning at the proximal portion, with the guidewire being received into guidewire lumen 30. The physician or other user continues to advance device 16 until the distal end region, including stent 56, is positioned at the treatment site, e.g. a lesion 72 along an artery 74 (Figure 6). Preferably distal tip 26 is beyond lesion 72. Stent 56, still maintained within the sheath, is axially aligned with the lesion. Sheath 22 remains in the stent retaining state.

With device 16 thus positioned, the physician maintains stainless steel tube 42 substantially fixed while moving valve 34 in the proximal direction. This moves outer catheter 18 proximally relative to the inner catheter, drawing outer sheath layer 48 proximally as well. This also proximally moves tip 26, i.e. the location at which sheath 22 is turned back upon itself. Meanwhile, inner catheter 28 abuts stent 56 to prevent any substantial proximal migration of the stent. Consequently the membrane is rolled or peeled from its surrounding relation to the stent, allowing the stent to radially self-expand progressively, beginning at its distal end (Figure 7).

Continued retraction of sheath 22 results in complete stent release (Figure 8). Stent 56 has radially self-expanded to a diameter up to 30 times the diameter of outer catheter 18. When sheath 22 is fully retracted, the distal end of the inner catheter becomes the distal tip of the device. Then, device 16 is advanced distally to axially align balloon 58 within stent 56. Following this alignment, fluid under pressure is supplied to balloon 58 via balloon inflation lumen 64, to expand the balloon against stent 56. The pressure from dilatation balloon 58 achieves several beneficial results. First, stent 56 is radially pressed into a more firm engagement with surrounding tissue of the arterial wall, to reduce the risk of stent migration and facilitate more laminar blood flow. Secondly, the added radial expansion is accompanied by an axial shortening of the stent, to more closely approximate a final stent axial dimension that otherwise might occur over a longer period of time

(approximately 1 hour to 1 day). This permits a more reliable determination of whether stent 56 is sufficiently long to cover lesion 72.

With stent 56 in place and pressed against artery 74, balloon 58 is evacuated and device 16 is proximally withdrawn. Guidewire 32 can be withdrawn as well, or left in place to permit advancing any device contemplated for a further procedure.

As best seen in Figures 8 and 9, when outer catheter 18 is retracted (i.e. moved proximally relative to inner catheter 28), it draws sheath 22 proximally as well, so that the rolling membrane eventually overlies and surrounds dilatation balloon 58. The axial length of the sheath is sufficient to provide sheath extension proximally of the dilatation balloon, so that the balloon is completely surrounded and covered. For example, the sheath axial length is sufficient if, with the sheath in the stent retaining state, the combined axial length of inner and outer sheath layers 46 and 48 exceeds the axial distance from distal end 54 to proximal neck 60.

The primary advantage of this configuration is that the rolling membrane, in addition to retaining the stent before retraction, provides a protective layer between tissue and the dilatation balloon after retraction. If the dilatation balloon were to burst during high pressure angioplasty, or if a tear or other fault allowed dilatation fluid to exit the balloon, sheath 22 would cause the dilatation fluid to flow proximally into lumen 20 of the outer catheter, thus protecting surrounding arterial tissue against exposure to exploding or jetting dilatation fluid. Also, as balloon 58 is inflated (Figure 9), sheath 22 provides a layer between the dilatation balloon and stent 56, preventing any damage to the balloon that might result from direct contact with the stent.

The structure and material of sheath 22 will generally be chosen to provide sufficient strength to counteract the restoring force of elastically compressed stent 56 during delivery while providing sufficient elasticity so that the sheath does not unduly interfere with dilatation of balloon 58. In certain applications a recovery metal stent is advantageous. The sheath, when not required to constrain a self-expanding stent during delivery, can be substantially more elastic.

The expanded balloon acts through sheath 22 to press stent 56 radially outward and against the surrounding arterial tissue. Momentarily, this radially expands and axially shortens stent 56 beyond a state of equilibrium at which the respective restoring forces within the stent and within surrounding tissue

counterbalance one another. When balloon 58 is evacuated and withdrawn, stent 56 slightly radially contracts and axially elongates to re-establish equilibrium. Thus stent 56 is caused to overexpand and then contract radially into equilibrium. As a result, the fluid flow path in the artery is smoother and flow is more laminar. With flow turbulence reduced, the potential for thrombus formation in the area of the stent likewise is reduced. The balloon expansion of the stent also enables the physician to more reliably confirm that the implanted stent has sufficient length relative to the lesion under treatment.

Following balloon evacuation, the distal region of the device reassumes the shape shown in Figure 8, whereby the device is easily proximally withdrawn to leave the stent in place.

Figure 10 shows the distal region of an alternative stent deployment device 80. Device 80 includes an inner catheter 82 with a guidewire lumen 84 that accommodates a guidewire 86. An outer catheter 88 has a catheter lumen 90 containing the inner catheter. A tubular sheath 92 includes a first end 94 mounted to the distal end 96 of the inner catheter, and a second end 98 mounted to the distal end 100 of outer catheter 88. A radially self-expanding stent 102 extends distally of the inner catheter, maintained in an axially elongated and radially compressed state. Device 80 differs from device 16 primarily in that outer catheter 88 extends distally beyond the inner catheter along the stent, and thus cooperates with an inner sheath layer 104 to maintain the stent under radial compression. Sheath 92 is turned back upon itself to provide a distal turn 106 and a relatively short outer sheath layer 108. Outer layer 108 and inner layer 104 converge to form a tapered distal tip of the device.

A dilatation balloon 110 is mounted to inner catheter 82 near distal end 96, and expandable in the same manner as dilatation balloon 58. When retracted, outer catheter 88 is proximal of balloon 110, so that sheath 92 once again overlies and surrounds the dilatation balloon to perform its protective function. Again, the combined length of the inner and outer sheath layers, in this case primarily the length of inner layer 104, exceeds the distance from the inner catheter distal end to the balloon proximal end.

Another feature of device 80 concerns guidewire lumen

84. The guidewire lumen does not run the length of inner catheter 82 as before, but ends just proximally of dilatation balloon 110. An aperture 112 through the catheter, open to lumen 84, allows guidewire 86 to exit the inner catheter. An elongate slit 114 through outer catheter 88 runs axially along the outer catheter and allows the guidewire to exit deployment device 80. When the device is in the stent retaining state, aperture 112 of the inner catheter is axially aligned with the distal end of slit 114. This feature is advantageous for procedures that require shorter guidewires or one or more guidewire exchanges, as is explained in the aforementioned PCT application, Publication No. WO 94/15549.

Figures 11 and 12 illustrate a stent retaining sheath 118 formed according to a further alternative embodiment of the invention. Sheath 118 is doubled over upon itself to provide inner and outer sheath layers 120 and 122 that surround a radially self-expanding stent 124, to maintain the stent in a radially compressed, axially elongated state against a restoring force. The distal portions of sheath layers 120 and 122 converge to provide a tapered distal tip 126 that terminates at a distal end 128. The proximal end of the inner sheath layer is mounted to an inner catheter 130, while the proximal end of outer layer 122 is attached to an outer catheter 132. As before, outer layer 122 is movable proximally to roll sheath 118 from its surrounding relation to the stent, whereby the stent progressively radially self-expands.

Several filaments 134 are embedded into sheath 118 and extend axially along outer sheath layer 122. Filaments 134 preferably are formed of a high modulus of elasticity fiber such as that sold under the brand name Kevlar, or Dacron fibers. Filaments 134 lend rigidity in the axial direction, for improved "pushability" of the device through arterial and other passageways.

Figures 13 and 14 illustrate a further embodiment device 140 in which an inner balloon catheter 142 is contained within a lumen 144 of an outer catheter 146. Balloon catheter 142 includes a lumen for a guidewire. A dilatation balloon 148 is mounted to catheter 142 near its distal end, and is in fluid communication with a balloon dilatation lumen of the catheter, through which a fluid under pressure can be supplied to the balloon to expand the balloon.

A tubular sheath 150 is fixed at one end to a distal end 152 of the outer catheter. The opposite end of the sheath is fixed to balloon catheter 142, but not at

its distal end. Rather, the sheath is fixed at a location proximal relative to balloon 148, as indicated at 154. Consequently a substantial portion of a sheath inner layer 156 surrounds the balloon. A distal portion of the inner layer extends beyond distal end 158 of the inner catheter, to surround and contain a stent 160 in a radially reduced delivery state as described in connection with device 16. Likewise, the sheath includes an outer sheath layer 162, and the sheath is modified to form a distal tip 164 in the manner previously explained.

Proximal movement of outer catheter 146, relative to balloon catheter 142, rolls sheath 150 in the proximal direction to release stent 160. As seen in Figure 14, retraction of the sheath leaves dilatation balloon 148 exposed, rather than surrounded by the sheath as in the first embodiment. The primary advantage of this embodiment (Figures 13 and 14) is that sheath 150 can have a relatively high elastic modulus for confining a radially self-expanding stent having a higher spring constant. The sheath need not have sufficient elasticity to accommodate dilatation balloon expansion in this embodiment. In certain applications, this advantage outweighs the loss of the sheath as a surrounding, protective layer over the dilatation balloon.

If desired, sheaths 92, 118 and 150 can incorporate a controlled narrowing of the sheath layers near the distal tip, as explained above in connection with Figure 5, to reduce the risk of damage to tissue during advancement of the device to the intended treatment site. The sheaths surround their respective stents and maintain the stents radially compressed, while in each case deriving added axial stiffness from the stent restoring force. The stents are maintained distally of their respective inner catheters, resulting in smaller diameter devices able to enter narrower arterial passages. In addition to their smaller diameters, the resulting devices exhibit improved pushing and tracking characteristics. If desired, axial stiffness can be enhanced by a distal extension of the outer catheter, or by axial filaments embedded into the sheath. After release of the stent at the treatment site, the retracted sheath can surround the dilatation balloon to provide an added protective layer useful in high pressure angioplasty. Alternatively, the sheath can be attached at a point where it exposes the dilatation balloon when retracted.

The preceding detailed description and drawings illustrate and explain several preferred embodiments and are not to be construed as limiting the scope of the present invention.

What is claimed is:

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CLAIMS

1. A device for deploying an expandable stent at a treatment site within a body; comprising:

a first catheter (28,82,130,142) having a proximal end region and a distal end region;

a stent retaining member (22,92,118,150) disposed at the distal end region of the first catheter and including an inner layer (46,104,120,162) extending distally beyond the first catheter, said member being turned back upon itself to form an outer layer (48,108,122,162) extending toward the first catheter, said inner layer adapted to retain an expandable stent (56,102,124,160) in a reduced state along an axial length of the stent with the stent located distally of the first catheter; and

a means (34,44) operable to displace the outer layer relative to the first catheter, to remove the member from its retaining relation to the stent, thus to release the stent for expansion at the treatment site.

2. The device of claim 1 wherein:

a distal end of the first catheter is positioned near a proximal end of the stent when the member retains the stent, to abut the stent and thereby prevent any substantial proximal migration of the stent as the member is removed.

3. The device of claim 1 wherein:

said member (22,92,118,150) is a sheath that surrounds the stent when retaining the stent, said stent (56,102,124,160) is radially self-expanding and maintained in a radially compressed state when surrounded by the sheath, and the stent progressively radially self-expands as the sheath is removed from its surrounding relation to the stent.

4. The device of claim 3 wherein:

the first catheter (28,82,130,142) includes a catheter wall that defines a guide wire lumen (30,84) open to the distal end, and the sheath when in the retaining state defines a distal extension of the guidewire lumen.

5. The device of claim 4 further including:

an opening (112) through the catheter wall near the distal end, for admitting a guidewire into the guidewire lumen to run distally along said distal extension of the guidewire lumen.

6. The device of claim 3 wherein:

said sheath (22,92,118,150) comprises a rolling membrane, and said inner layer and outer layer are tubular.

7. The device of claim 6 wherein:

said inner layer (46,104,120,156) and outer layer (48,108,122,162), when the rolling membrane is in the stent retaining state, converge in the distal direction along respective distal layer portions (66,68) to form in the rolling membrane a tapered distal tip (26,106,128,164).

8. The device of claim 1 further including:

a stiffening means (134), extending axially at least along the outer layer, for enhancing axial rigidity of the member.

9. The device of claim 1 wherein:

said moving means (34,44) operable to displace the outer layer include a second catheter (18,88,132,146) having a second catheter lumen along substantially the entire length thereof, and wherein the first catheter is contained within the second catheter lumen.

10. The device of claim 9 wherein:

the member (22,92,118,150) comprises a fluid tight tubular rolling membrane connected to the first and second catheters in fluid tight fashion, to enable introduction of a fluid via the second catheter lumen into a region between the inner and outer layers.

11. The device of claim 10 further including:

a micropore (69) through said outer layer to permit release of a fluid from said region into the body.

12. The device of claim 1 further including:

a dilatation balloon (58,110,148) mounted to the first catheter along the distal end region, and a balloon dilation lumen (64) along the first catheter for supplying a fluid under pressure to the dilatation balloon.

13. The device of claim 12 wherein:

the member is mounted to the first catheter at a location distally of the dilatation balloon; and

the combined axial length of the inner and outer layers exceeds an axial distance from said location to a proximal end of the dilatation balloon.

14. The device of claim 12 wherein:

said member is mounted to the first catheter at a location proximally of the dilatation balloon.

15. An apparatus for deploying a radially expandable stent at a treatment site within a body lumen; comprising:

an elongate first catheter (28,82,130,142) having a proximal end and a distal end;

an elongate second catheter (18,88,132,146) having a proximal end and a distal end, and a catheter lumen (20,90,144) running along the second catheter and open to the distal end of the second catheter, wherein the first catheter is contained within the catheter lumen; and

a tubular, pliable and flexible sheath (22,92,118,150), and means for connecting a first end of the sheath to the first catheter, and for connecting a second end of the sheath to a distal end of the second catheter;

wherein the first catheter and the second catheter are movable relative to one another to position the sheath in a stent retaining state with the sheath adapted to surround a radially expandable stent (56,102,124,160) along an axial length of the stent, with the first catheter and the sheath cooperating to maintain the stent distally of the first catheter and in a radially reduced state to facilitate use of the first and second catheters to deliver the stent to a treatment site within a body lumen; and

wherein the first catheter and the second catheter are further moveable relative to one another to roll the sheath proximally from its surrounding relation to the stent, thus to release the stent for radial expansion at the treatment site.

16. The apparatus of claim 15 wherein:

said stent is radially self-expanding and confined in a radially compressed state when surrounded by the sheath, and radially self-expands as the sheath is rolled proximally from the stent.

17. The apparatus of claim 15 wherein:

said sheath, when in the stent retaining state, includes an inner sheath layer (46,104,120,156) extended distally from the distal end of the first catheter, and is turned back upon itself to provide an outer sheath layer

(48,108,122,162) extended proximally to the distal end of the second catheter and surrounding the inner sheath layer.

18. The apparatus of claim 17 wherein:

the connections of the sheath with the respective distal ends of the first and second catheters are fluid tight, to facilitate introduction of a fluid to a location between the inner sheath layer and the outer sheath layer, via the catheter lumen.

19. The apparatus of claim 18 further including:

a micropore (69) through the sheath outer layer, for releasing fluids from said location into the body cavity.

20. The apparatus of claim 17 further including:

an axially extended stiffening means (134) for enhancing the axial rigidity of the sheath, at least along the outer sheath layer.

21. The apparatus of claim 15 further including:

a flexible dilatation balloon (58,110,148) mounted to the first catheter near the distal end of the first catheter, and a balloon inflation lumen (64) along the first catheter for supplying a fluid under pressure to the dilatation balloon.

22. The apparatus of claim 21 wherein:

the sheath is connected to a distal end of the first catheter; and

an axial length of the sheath, between the first and second ends, exceeds an axial distance from the distal end of the first catheter to a proximal end of the dilatation balloon.

23. The apparatus of claim 21 wherein:

the sheath is connected to the first catheter at a location proximally of the dilatation balloon.

24. A process for deploying an expandable stent at a treatment site within a body, comprising:

providing a member (22,92,118,150) attached to a catheter (28,82,130,142) near a distal end thereof, to engage an expandable stent (56,102,124,160) over a length of the stent and thereby maintain the stent distally of said distal end in a reduced state;

with the stent maintained in the reduced state, delivering the stent with the catheter to a treatment site within a body; and

while holding the catheter substantially stationary to maintain the stent at the treatment site and distally of said distal end, withdrawing the member from its retaining relation to the stent, to release the stent for expansion at the treatment site.

25. The process of claim 24 further including:

after said release and expansion of the stent, moving the catheter distally relative to the stent until a dilatation balloon (58,110,148) mounted near the distal end of the catheter is surrounded by the stent, and then expanding the dilatation balloon to further radially expand the stent.

26. The process of claim 25 wherein:

said member comprises a sheath including an inner sheath layer (46,104,120,156) extended distally away from the catheter and surrounding the stent, and turned back upon itself to provide an outer sheath layer (48,108,122,162) surrounding the inner sheath layer and extended proximally toward the catheter; and

wherein said step of withdrawing the member includes proximally moving the outer layer to progressively roll the sheath away from its surrounding relation to the stent.

27. The process of claim 26 further including:

prior to proximally moving the sheath outer layer, injecting a fluid into a region between the inner sheath layer and the outer sheath layer, to reduce friction between said layers.

28. An apparatus for deploying a radially expandable stent at a treatment site within a body lumen and for forcing the stent against the body lumen after deployment; said apparatus comprising:

an elongate balloon catheter (28,82,130,142) having a proximal end and a distal end;

a stent releasing means (18,88,132,146) disposed along the balloon catheter and having a proximal end;

a sheath (22,92,118,150), and means for connecting a first end of the sheath to the balloon catheter and connecting a second end of the sheath to the stent releasing means; and

a flexible dilatation balloon (58,110,148) mounted to the balloon catheter near said distal end of the balloon catheter, and a balloon inflation lumen

(64) along the balloon catheter for supplying a fluid under pressure to the dilatation balloon;

wherein the sheath is positionable in a stent retaining state with the sheath surrounding and engaging a radially expandable stent along an axial length of the stent when at least a portion of the stent extends distally of said balloon catheter, thus to maintain the stent in a radially reduced state to facilitate use of the balloon catheter to deliver the stent to a treatment site within a body lumen; and

wherein the stent releasing means is movable proximally relative to the balloon catheter to roll the sheath away from its surrounding relation to the stent, thus to release the stent for radial expansion at the treatment site.

29. The apparatus of claim 28 wherein:

the first end of the sheath is connected to the balloon catheter at a location (54,96) distally of the dilatation balloon; and

wherein an axial length of the sheath from its first end to its second end exceeds an axial distance from the first end of the sheath to a proximal end of the dilatation balloon.

30. The apparatus of claim 28 wherein:

said first end of the sheath is connected to the catheter at a location (154) proximally of the dilatation balloon.

31. The apparatus of claim 28 wherein:

said stent is radially self-expanding and maintained in a radially compressed state when surrounded by the sheath, and self-expands as the sheath is rolled away from the stent.

32. The apparatus of claim 28 wherein:

said stent releasing means (18,88,118,150) includes a release catheter having a catheter lumen along substantially the entire length thereof, and wherein the balloon catheter is contained within
the catheter lumen.

33. The apparatus of claim 32 wherein:

the second end of the sheath is mounted to a distal end of the release catheter.

34. The apparatus of claim 28 wherein:

said sheath, when in the stent retaining state, includes an inner layer (46,104,120,156) extended along and engaging the stent, and is turned back upon itself to provide an outer layer (48,108,122,162) extended along and surrounding the inner layer.

35. The apparatus of claim 34 wherein:

the sheath and the connecting means are fluid tight, to facilitate introduction of a fluid via the catheter lumen to a location between the inner sheath layer and the outer sheath layer.

36. The apparatus of claim 28 wherein:

the first end of the sheath is mounted to the balloon catheter at said distal end, and the stent when maintained in the radially reduced state is located entirely distally of said distal end.

37. A device for releasably securing a radially expandable stent near a distal end of an elongate catheter, said device comprising:

a stent retaining sheath (22,92,118,150) mounted to a distal end region of a catheter (28,82,130,142), said sheath being positionable in a stent retaining state in which the sheath surrounds and engages a radially expandable stent (56,102,124,160) along an axial length of the stent, thus to maintain the stent in a radially reduced state with the stent located distally of the catheter, to facilitate use of the catheter for delivery of the stent to a treatment site within a body lumen;

wherein the sheath is movable proximally relative to the catheter to allow a rolling of the sheath away from its surrounding relation to the stent, to release the stent for radial expansion at the treatment site.

38. The device of claim 37 wherein:

the sheath when surrounding the stent includes an inner sheath layer (46,104,120,156) surrounding and engaging the stent, and is turned back upon itself to provide an outer sheath layer (48,108,122,162) surrounding the inner sheath layer; and

said rolling is accomplished by moving the outer sheath layer proximally relative to the stent.

39. The device of claim 38 wherein:

said inner sheath layer surrounds a radially

self-expanding stent and maintains the stent in a radially compressed state and, when progressively rolled away from its surrounding relation to the stent, releases the stent for radial self-expansion.

40. The device of claim 38 wherein:

said sheath comprises a rolling membrane, and said inner sheath layer and outer sheath layer are tubular; and

said inner sheath layer and outer sheath layer, when the rolling membrane is in the stent retaining state, converge in the distal direction along respective sheath layer portions (66,68) to form in the rolling membrane a tapered distal tip.

41. The device of claim 37 further including:

a stiffening means (134) extending axially along the sheath for enhancing axial rigidity.

42. The device of claim 38 further including:

a stent releasing means (18,88,132,146) attached to the outer sheath layer and operable from a proximal end of the catheter to move the outer sheath layer proximally relative to the catheter.

43. The device of claim 38 wherein:

the sheath is fluid tight to facilitate introduction of a fluid into a region between the inner and outer sheath layers.

44. A device for deploying a radially expandable stent at a treatment site within a body lumen, comprising:

an elongate delivery catheter (28,82,130,142) having a proximal end region and a distal end region;

a tubular stent retaining sheath (22,98,118,150) mounted to a distal end region of the delivery catheter and extended distally from the delivery catheter whereby the sheath is adapted to surround a radially expandable stent (56,102,124,160) along an axial length of the stent, to maintain the stent in a radially reduced state to facilitate use of the delivery catheter to deliver the stent to a treatment site within a body lumen, said sheath, distally of the stent, converging in the distal direction to form a tapered distal tip (26,106,128,164); and

a stent releasing means (18,88,132,146) operatively coupled to the sheath and movable relative to the delivery catheter to roll the sheath away from its

surrounding relation to the stent, to release the stent for radial expansion at the treatment site.

45. The device of claim 44 wherein:

said sheath, when so maintaining the stent, includes an inner sheath layer (46,104,120,156) extended distally from the delivery catheter and engaging the stent, said sheath further being turned back upon itself at said distal tip to provide an outer sheath layer (48,108,122,162) extended proximally toward the delivery catheter and surrounding the inner sheath layer; and

the outer sheath layer and the inner sheath layer, in the region of said distal tip, are progressively narrowed in the distal direction whereby the thickness of said distal tip diminishes in said distal direction.

46. The device of claim 45 wherein:

said inner and outer sheath layers, in the region of the distal tip, provide a transition region over which the hardness of the sheath diminishes in the distal direction, whereby said distal tip is softer than the remainder of the sheath.

47. The device of claim 46 wherein:

a distal end of the delivery catheter is near a proximal end of the stent when the stent is surrounded by the sheath, to prevent any substantial travel of the stent, proximally relative to the delivery catheter and sheath, when surrounded by the sheath.

48. The device of claim 45 wherein:

said stent releasing means (18,88,132,146) includes a release catheter surrounding the delivery catheter and coupled at its distal end to the outer sheath layer, and movable proximally relative to the delivery catheter to move the outer sheath layer proximally, thus to roll the sheath away from the stent.

FIG. 1

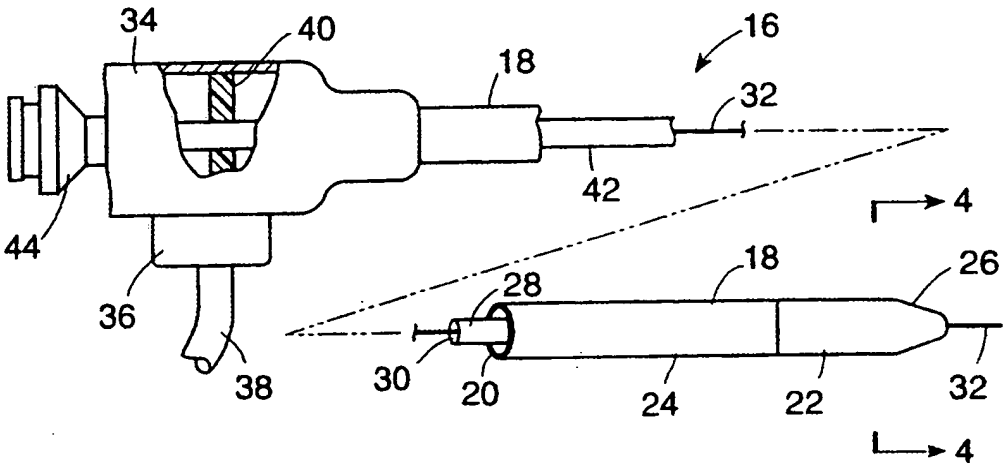


FIG. 2

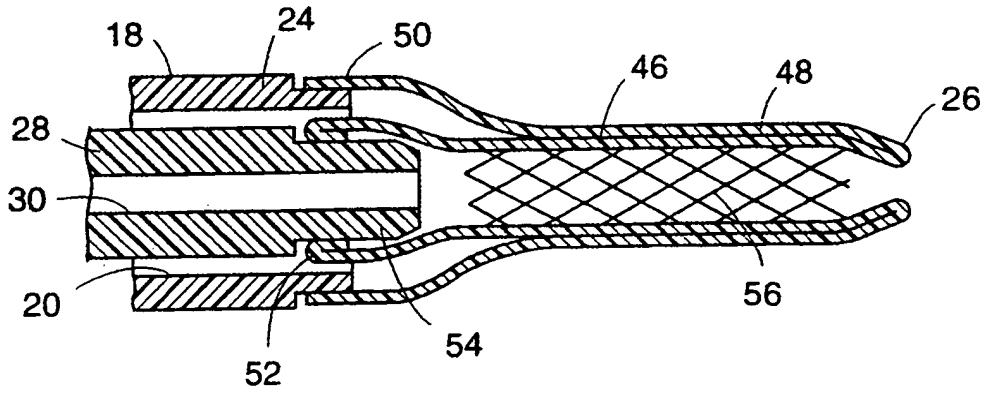


FIG. 3

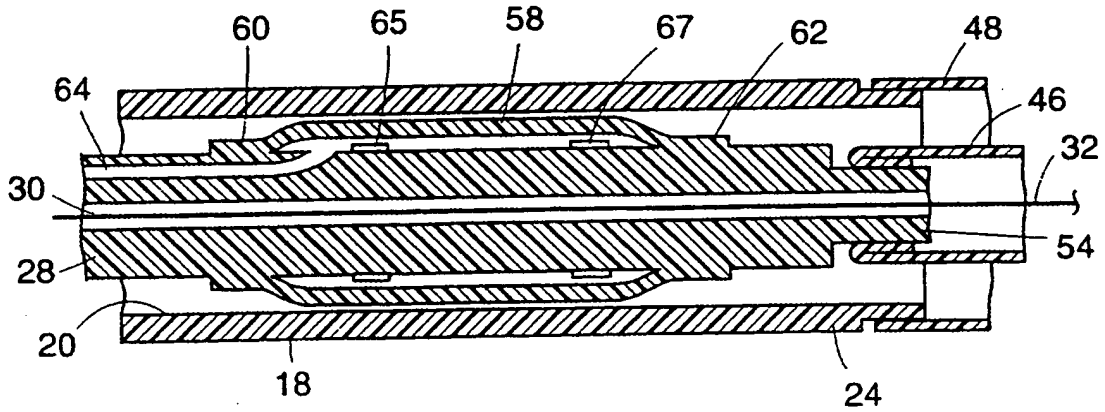


FIG. 4

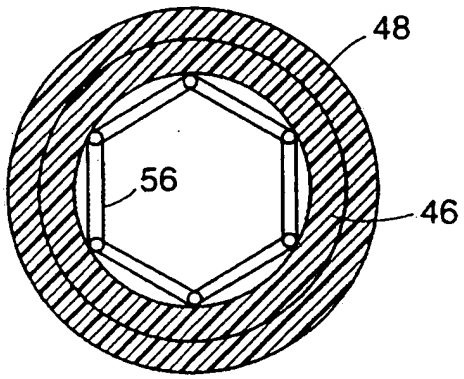
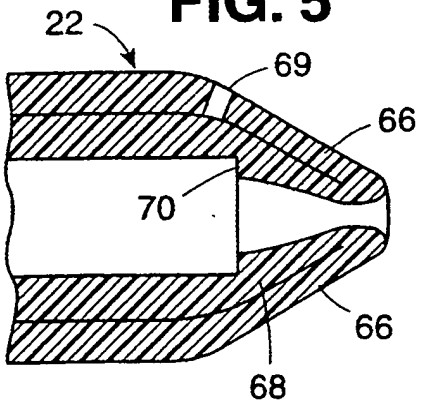


FIG. 5



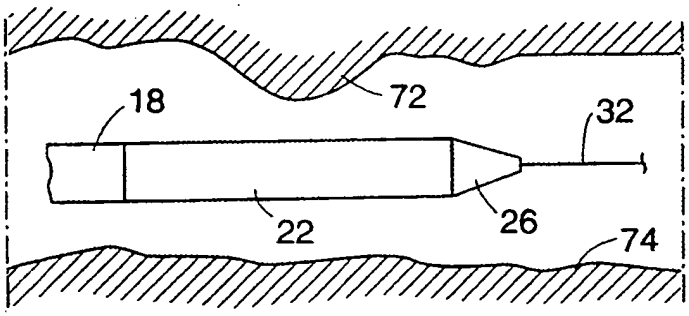


FIG. 6

FIG. 7

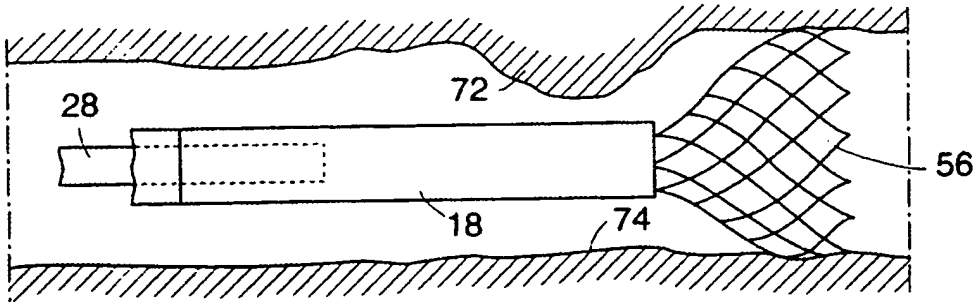


FIG. 8

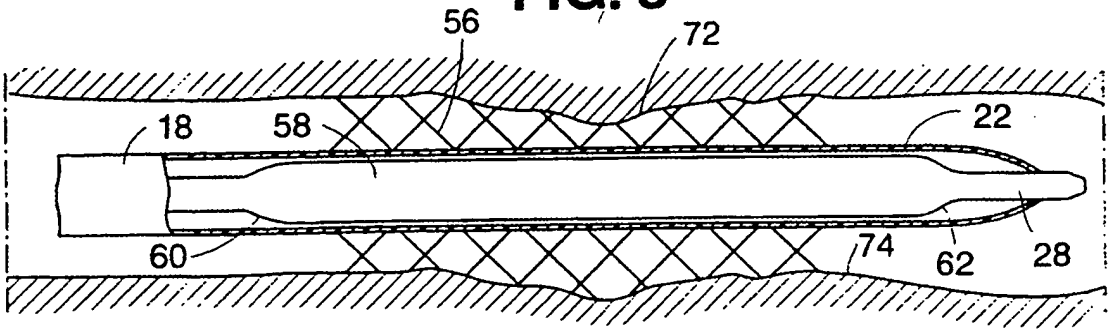


FIG. 9

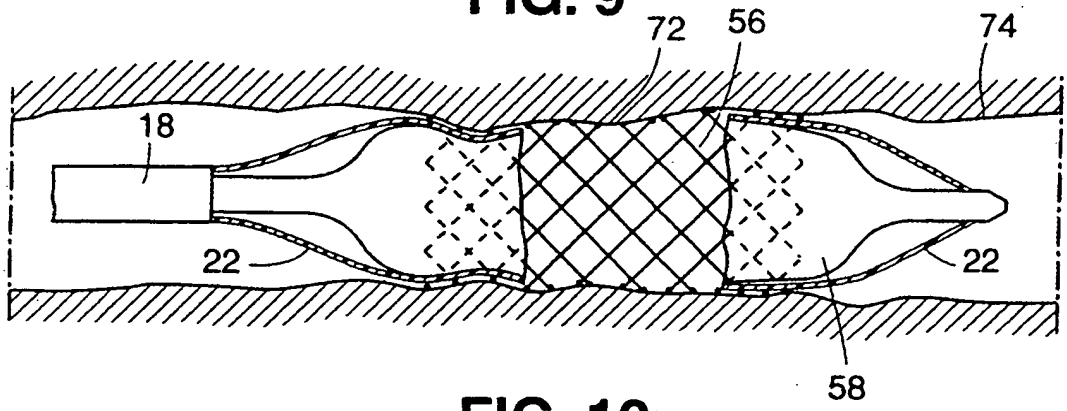


FIG. 10

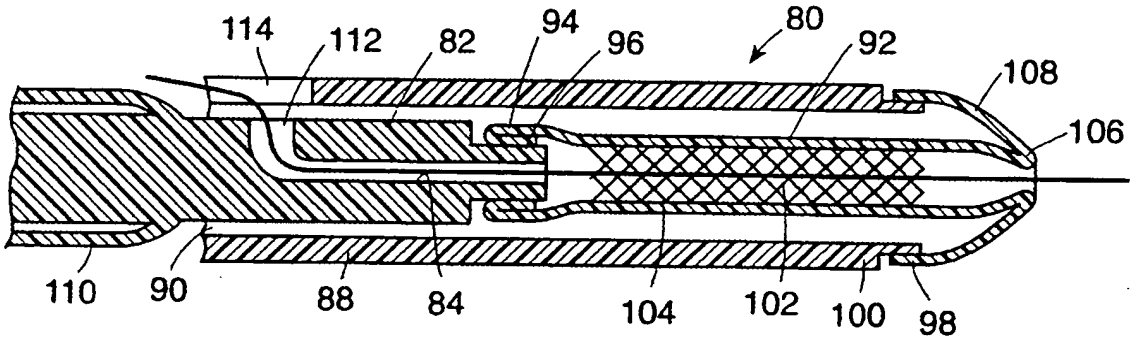


FIG. 11

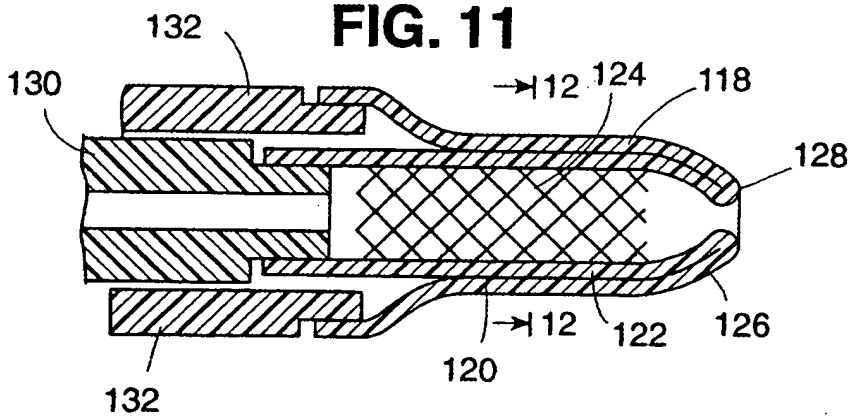


FIG. 12

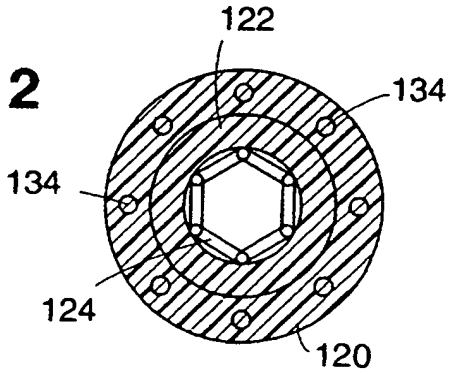


FIG. 13

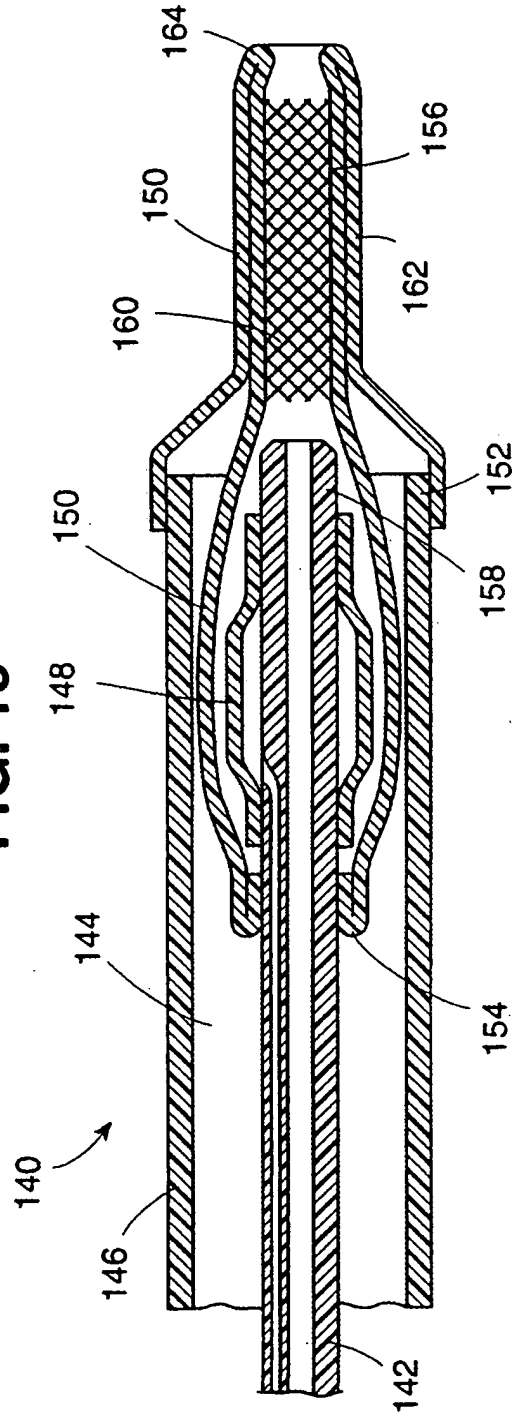

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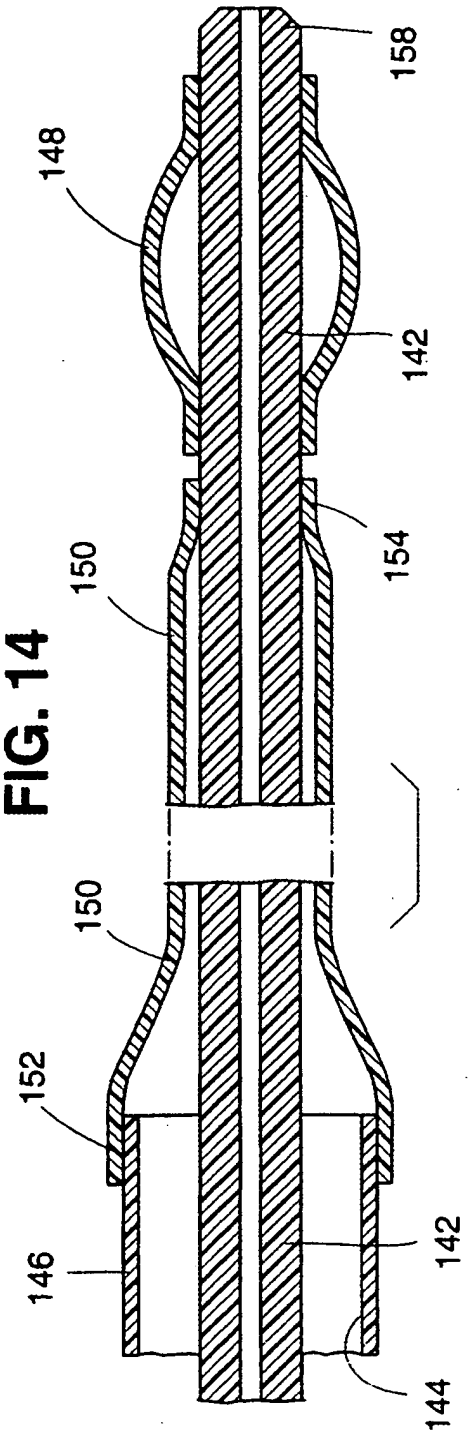
FIG. 14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INTERNATIONAL SEARCH REPORT

Inter. ..al Application No
PCT/IB 96/00146

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,94 15549 (SCHNEIDER (USA)) 21 July 1994 cited in the application see page 16, line 17 - page 18, line 17; claim 18; figures 9-13	1-7,9, 12, 15-17, 21,28, 37-40,44
Y	US,A,5 224 953 (MORGENTALER) 6 July 1993 see abstract; figures 3-5	1-7,9, 12, 15-17, 21,28, 37-40,44
A	US,A,4 732 152 (WALLSTEN) 22 March 1988 cited in the application see the whole document	1,15,28, 37,44

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 July 1996	24.07.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Klein, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inten ial Application No
PCT/IB 96/00146

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 554 579 (SCHNEIDER (EUROPE)) 11 August 1993 see the whole document	1,15,28, 37,44
A	US,A,4 655 771 (WALLSTEN) 7 April 1987 cited in the application see column 8, line 7 - line 62; figure 11	1,15,28, 37,44
A	US,A,5 180 362 (WORST) 19 January 1993	
A	WO,A,93 22986 (SCHNEIDER (USA)) 25 November 1993	

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

national application No.

PCT/IB 96/00146

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 24-27
because they relate to subject matter not required to be searched by this Authority, namely:
Method for treatment of the human body by surgery.
See Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter. .tal Application No
PCT/IB 96/00146

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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		DE-T-	3590638	10-12-87
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		CA-A-	1239755	02-08-88
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		DE-T-	3342798	10-01-85
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern al Application No
PCT/IB 96/00146

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PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00 — A1

(11) International Publication Number: **WO 97/32623**

(43) International Publication Date: 12 September 1997 (12.09.97)

(21) International Application Number: PCT/US97/03543

(22) International Filing Date: 7 March 1997 (07.03.97)

(30) Priority Data:
08/612,230 7 March 1996 (07.03.96) US
08/749,683 15 November 1996 (15.11.96) US

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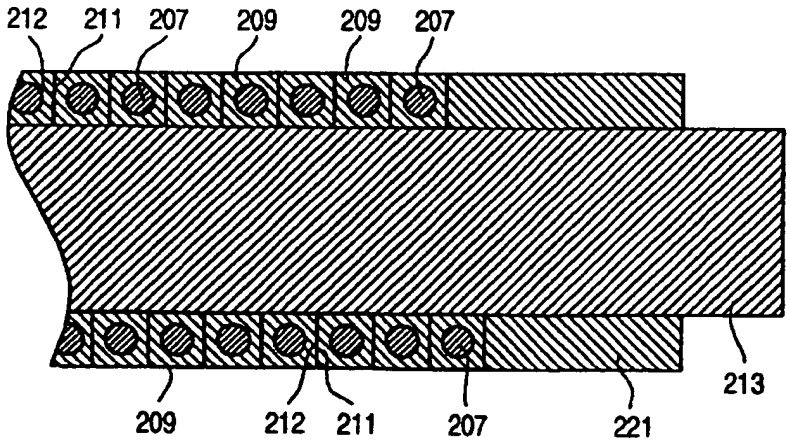
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: CANNULA AND METHOD OF MANUFACTURE AND USE



(57) Abstract

An elongate member (207) is coated with a coating (209), preferably by co-extrusion, and the coated elongate member (207) is wound in a helical manner around a mandrel (213). The coated elongate member (207) preferably has a square cross-sectional shape so that adjacent portions of the coated elongate member (207) engage one another when the coated elongate member (207) is wound around the mandrel (213). The coated elongate member (207) is then heated so that the coating (209) on adjacent portions of the coated elongate member (207) fuse together to form an integral structure. Another layer (225) of material may be provided on the radially inner or outer wall of the coated elongate member (207).

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CANNULA AND METHOD OF MANUFACTURE AND USE

BACKGROUND OF THE INVENTION

The present invention is directed to reinforced hollow tubes and their methods of manufacture and use. A specific application of the present invention is for arterial and venous cardiopulmonary bypass (CPB) cannulas. The present invention is particularly useful as the arterial return cannula for the cardiopulmonary bypass system described in co-pending U.S. Patent Application No. 08/282,192 which is incorporated herein by reference. The CPB system has an arterial return cannula which is used to return oxygenated blood to the patient. An aortic occlusion catheter passes through the arterial cannula. The aortic occlusion catheter is used to block blood flow through the ascending aorta and deliver cardioplegic fluid to arrest the heart for performing surgery on the heart and great vessels. The aortic occlusion catheter is inserted through the same lumen in the arterial cannula which is used to return arterial blood to the patient so that the arterial blood essentially passes in the annular space between the aortic occlusion catheter and the arterial return cannula.

An advantage of the CPB system described above is that only one opening in the patient's arterial system is required for both delivery of cardioplegic fluid and return of arterial blood. In order to achieve optimum blood and cardioplegic fluid flow rates, the wall of the arterial cannula must be minimized while retaining enough structural integrity to prevent kinking and/or cracking. The present invention is particularly useful in providing a thin walled cannula which may be used as an arterial return cannula for the system described above.

A known method of making a reinforced cannula is to dip a mandrel in a polymer solution and wrap a metal wire over the polymer. The mandrel is then dipped again to encase the metal wire between two layers of polymer.

Another known method of making a reinforced cannula is to extrude a polymer tubing, wrap a metal wire around the polymer tubing, and extrude another polymer layer over the metal wire.

A problem with the known methods of manufacturing a reinforced cannula is that the spacing between adjacent wires must be relatively large to ensure that the polymer flows between adjacent coils so that the two polymer layers bond together to form an integrated structure. Unfortunately, the relatively large spacing requires a relatively thick polymer layer to provide the necessary strength since the wire has a large pitch. The relatively thick polymer layer is also required to ensure that a sufficient amount of polymer is provided to fill the relatively large space. The resulting cannula has a relatively thick wall.

Thus, a specific object of the present invention is to provide a new method of manufacturing reinforced tubing and, in particular, cannulas for venous withdrawal and arterial return of blood for a cardiopulmonary bypass system.

SUMMARY OF THE INVENTION

The present invention solves the problems associated with prior art cannulas by providing a reinforced, thin-walled cannula and a method of manufacturing the reinforced, thin-walled cannula.

An elongate member, such as a steel or polymer wire, is coated with a coating, preferably a polymer, thereby forming a coated elongate member. A preferred method of coating the material is to coextrude the material over the elongate member. The coated elongate member is then wound helically around a mandrel and heated so that the coating on adjacent parts of the elongate member bond together. The coated elongate member is then mounted to a cannula body.

In a preferred method, the coated elongate member is formed so that opposing sides of the coated elongate member engage one another when the coated elongate member is wrapped around the mandrel. A preferred cross-sectional shape is substantially square. An advantage of the present invention is that the coating does not need to flow between adjacent portions of the helically-wound member since the coated elongate members are configured to have sides which engage one another. In another aspect of the invention, the coated elongate member is compressed after being wound around the mandrel. The coated elongate member is preferably compressed with a heat shrink tube placed over the coated elongate member before heating. The shrink tube compresses the polymer to further ensure bonding between adjacent portions of the coated elongate member.

In another aspect of the present invention, a layer is positioned over and/or below the coated elongate member. The layer is preferably positioned over the coated elongate member and is applied as a tube of material having a larger inner diameter than the largest outer diameter of the coated elongate member. The tube is expanded, preferably by inflating the tube, and the coated elongate member is positioned inside the tube. The tube is then deflated so that it contracts around the coated elongate member. The tube and coated elongate member are then heated to fuse the elongate member and tube together to form an integrated structure. Although it is preferred to apply the layer as a tube, the layer may also be applied by dipping the coated elongated member in a suitable solution.

An advantage of the cannula of the present invention is that the cannula has a thin-walled construction while providing a lumen having a relatively large inner diameter. The lumen is particularly suited to receive an aortic occlusion catheter while still providing enough annular area between the catheter and lumen wall for return of arterial blood to sustain full CPB.

These and other aspects of the invention will become apparent with the following description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a front view of an arterial cannula and introducer sheath for use with an endoaortic occlusion catheter.

Fig. 2 is a cross sectional view of a hemostasis fitting for the arterial cannula and introducer sheath of Fig. 1.

Fig. 3 illustrates the cannula of Fig. 1 with the endoaortic occlusion catheter introduced into the catheter insertion chamber.

Fig. 4 illustrates the cannula of Figs. 1 and 2 with the endoaortic occlusion catheter introduced into the patient's femoral artery.

Fig. 5 illustrates a multifunction embodiment of the endoaortic occlusion catheter combined with the arterial cannula and introducer sheath.

Fig. 6 is a cross-sectional view of a cannula having a reinforced section coupled to a body.

Fig. 7 is a cross-sectional view of a coated elongate member wrapped around a mandrel.

Fig. 8 is a cross-sectional view of the coated elongate member of Fig. 7 after heating and removal from the mandrel.

Fig. 9 is a cross-sectional view of a second construction for the reinforced section.

Fig. 10 is a cross-sectional view of a third construction for the reinforced section.

Fig. 11 is a cross-sectional view of a fourth construction for the reinforced section.

Fig. 12 is a cross-sectional view of a fifth construction for the reinforced section.

Fig. 13 is a cross-sectional view of a sixth construction for the reinforced section.

Fig. 14 is a cross-sectional view of a seventh construction for the reinforced section.

Fig. 15 is a cross-sectional view of a eighth construction for the reinforced section.

Fig. 16 is a cross-sectional view of a ninth construction for the reinforced section.

Fig. 17 shows an exploded view of another arterial return cannula.

Fig. 18 shows the distal end of the arterial return cannula of Fig. 17 before heating.

Fig. 19 shows the distal end of the arterial return cannula of Fig. 18 after heating.

Fig. 20 shows an enlarged view of the distal end of an obturator used with the arterial return cannula of Fig. 17 along line A-A.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is directed to cannulas and their methods of manufacture. A particularly useful application of the present invention is for arterial and venous cardiopulmonary bypass cannulas.

Referring to Figs. 1-4, an endoaortic occlusion catheter 95 is coupled to a cannula 50 that is configured to serve as an arterial bypass cannula and an introducer sheath for introduction of the endoaortic occlusion catheter 95. By configuring the catheter 95 and cannula 50 in this manner, both devices are inserted through the same arterial opening which minimizes trauma to the patient. Use of the cannula 50 to receive an aortic occlusion catheter is merely an example of a use of the present invention and the cannula 50 may be used for any other purpose. Furthermore, the term cannula as used herein refers to any hollow body structure, such as a catheter or trocar, which is inserted into a patient's vascular system. The cannula 50 is coupled to a cardiopulmonary bypass system (not shown) for delivering oxygenated blood to the patient's arterial system. The aortic occlusion catheter 95 has a lumen which is coupled to a source of cardioplegic fluid (not shown). The lumen is coupled to an

outlet which is distal to the balloon 96. Cardioplegic fluid is delivered through the lumen and outlet for arresting a patient's heart when the patient is on full cardiopulmonary bypass. The balloon 96 occludes the ascending aorta to prevent oxygenated blood from reaching the coronary arteries and starting the heart prematurely.

The cannula 50 has a body 51 which is preferably made of a transparent, flexible, biocompatible polyurethane elastomer or similar material. In one preferred embodiment, the body 51 has a 45° beveled distal end 53, a proximal end 52, a blood flow lumen 57 extending between the proximal end 52 and the distal end 53, and an outflow port 91 at the distal end 53. Alternatively, the body 51 can have a straight cut distal end with a chambered or rounded edge. Optionally, a plurality of additional outflow ports may be provided along the length of body 51, particularly near distal end 53. The body 51 is tapered from the proximal end 52 to the distal end 53 and, in one preferred embodiment, the tapered body 51 is reinforced with a coil of flat stainless steel wire 54 embedded in the wall of the body 51. Adjacent to the proximal end 52 of the body 51, proximal to the reinforcing coil 51, is a clamp site 51 which is a flexible section of the body 51 that can be clamped with an external clamp, such as a Vorse type tube occluding clamp, forming a hemostatic seal to temporarily stop blood flow through the lumen 57 of the cannula 50. In a preferred embodiment, the body 51 has a length between about 10 cm and 60 cm, and preferably between about 12 cm and 30 cm. In one particular embodiment, the body 51 has a distal external diameter of approximately 7 mm or 21 French (Charrière scale) and a distal internal diameter of approximately 6.0 mm or 18 French. In a second particular embodiment, the body 51 has a distal external diameter of approximately 7.7 mm or 23 French (Charrière scale) and a distal internal diameter of approximately 6.7 mm or 20 French. Preferably, the proximal end 52 of the body 51 of either embodiment has an internal diameter of approximately 3/8 inch or 9.5 mm. The choice of which embodiment of the cannula 50 to use for a given patient will depend on the size of the

patient and the diameter of the artery chosen for the arterial cannulation. Generally, patients with a larger body mass will require a higher infusion rate of oxygenated blood while on cardiopulmonary bypass, therefore the larger arterial bypass cannula 50 should be chosen if the size of the artery allows.

An adapter assembly 65 is connected to the proximal end 52 of the body 51. In one preferred embodiment, the adapter assembly 65 and the body 51 are supplied preassembled as a single, sterile, ready-to-use unit. Alternatively, the adapter assembly 65 can be packaged and sold as a separate unit to be connected to the body 51 at the point of use. The adapter assembly 65 has a Y-fitting 58 which is connected to the proximal end 52 of the cannula body 51. The Y-fitting 58 has a first branch ending in a barbed connector 59 which is configured for fluid connection to tubing 92 from a cardiopulmonary bypass system, as shown in Fig 4. To prepare the arterial bypass cannula 50 for insertion into a peripheral artery, such as a patient's femoral artery or brachial artery, by an arterial cutdown or by a percutaneous Seldinger technique, a connector plug 71, which is molded of a soft, elastomeric material, is placed over the barbed connector 59. A tapered dilator 67 is passed through a wiper-type hemostasis seal 72 in the connector plug 71. The wiper-type hemostasis seal 72 is a hole through the elastomeric connector plug 71 that has a slight interference fit with the external diameter of the dilator 67. A series of ridges can be molded within the hemostasis seal 72 to reduce the sliding friction on the dilator 67 while maintaining a hemostatic seal. It is understood that any other type of hemostasis seal 72 may be used with the present invention. The dilator 67 has a tapered distal tip 69, a proximal hub 70 with a luer lock connector, and a guidewire lumen 79, sized for an 0.038 inch diameter guidewire, that runs from the distal tip 69 to the proximal hub 70. The diameter of the dilator 67 is such that the dilator 67 substantially fills the cannula lumen 57 at the distal end 53 of the cannula body 51. The length of the dilator 67 is such that the distal tip 69 of the dilator 67 extends approximately 2 to 5 cm, and more preferably 4 to 5

cm, beyond the beveled end 53 of the body 51 when the dilator hub 70 is against the connector plug 70. The dilator 67 may assume a bend 73 in it at the point where the dilator 67 passes through the Y-fitting 58 when the dilator 67 is fully inserted. One or more depth markers 74, 75 can be printed on the dilator 67 with a nontoxic, biocompatible ink. One depth marker 74 may be placed so that, when the marker 74 is just proximal to the hemostasis seal 72 on the elastomeric connector plug 71, the tapered distal tip 69 of the dilator 67 is just emerging from the beveled end 53 of the body 51. In one particular embodiment, the tapered dilator 67 is made of extruded polyurethane with a radiopaque filler so that the position of the dilator can be verified fluoroscopically.

A second branch of the Y-fitting 58 is connected to an extension tube 62 which terminates in a hemostasis valve 76 configured to receive the endoaortic occlusion catheter 95 therethrough (Figs. 3 and 4). The extension tube 62 has a flexible middle section which serves as a proximal clamp site 64 that can be clamped with an external clamp, such as a Vorse type tube occluding clamp, forming a hemostatic seal to temporarily stop blood flow through the lumen 63 of the extension tube 62. The lumen 63 of the extension tube 62 between the proximal clamp site 64 and the hemostasis valve 76 serves as a catheter insertion chamber 66, the function of which will be more fully explained in connection with Fig. 3. The hemostatic seal may, of course, be any other type of seal.

In a preferred embodiment of the arterial bypass cannula 50, the hemostasis valve 76 is a type of compression fitting known in the industry as a Tuohy-Borst adapter, however, any other suitable seal may be used. The adapter 76 is shown in greater detail in Fig. 2. The adapter 76 has a compressible tubular or ring-shaped elastomeric seal 83 that fits within a counterbore 79 in the fitting body 77. The elastomeric seal 83 is preferably made from a soft, resilient, self-lubricating elastomeric material, such as silicone rubber having a hardness of approximately 20-50 and preferably 40-50 Shore A durometer. The elastomeric seal 83 has a central passage 84 with a beveled entry 85 on the proximal end of the

passage 84. The elastomeric seal 83 has a beveled distal surface 86 angled at about 45° which fits against a tapered seat 80 in the bottom of the counterbore 79 that is angled at about 60°. A threaded compression cap 87 screws onto the fitting body 77. The threaded cap 87 has a tubular extension 89 which fits within the counterbore 79 in the fitting body 77. An externally threaded section 88 on the proximal end of the tubular extension 87 engages an internally threaded section 81 within the proximal end of the counterbore 79. When the threaded cap 87 is screwed down onto the fitting body 77, the tubular extension 89 bears on the elastomeric seal 83 forcing it against the tapered seat 80 of the counterbore 79. The resultant force on the elastomeric seal 83 squeezes the elastomeric seal 83 inward to close off the passage 84 to make a hemostatic seal. When the threaded cap 87 is unscrewed again from the fitting body 77, the central passage 84 of the elastomeric seal 83 opens up again. The deliberate 15° mismatch between the angle of the beveled distal surface 86 of the elastomeric seal 83 and the tapered seat 80 of the counterbore 79 prevents the elastomeric seal 83 from binding and causes the passage 84 to open up reliably when the threaded cap 87 is unscrewed from the fitting body 87. An internal ridge 90 within the threaded cap 87 engages in a snap fit with an external ridge 82 on the proximal end of the fitting body 77 to keep the threaded cap 87 from being inadvertently separated from the fitting body 77 if the threaded cap 87 is unscrewed to the point where the threads 88, 81 are no longer engaged.

In one particular embodiment, the central passage 84 of the elastomeric seal 83 has an internal diameter of about 5 mm to allow clearance for inserting a catheter 95 with a shaft diameter of 3-4 mm through the adapter 76 without damaging the occlusion balloon 96 mounted on it. The adapter 76 is adjustable through a range of positions, including a fully open position for inserting the balloon catheter 96, a partially closed position for creating a sliding hemostatic seal against the shaft 97 of the catheter 95, and a completely closed position for creating a hemostatic seal with no

catheter in the passage 84. In an alternative embodiment, the passage 84 of the elastomeric seal 83 can be sized to have a slight interference fit with the shaft 97 of the catheter 95 when uncompressed. In this embodiment, the adapter 76 has positions which include a fully open position for creating a sliding hemostatic seal against the shaft 97 of the catheter 95, and a completely closed position for creating a hemostatic seal with no catheter in the passage 84. In a second alternative embodiment, a separate ring-like wiper seal (not shown) is added in series with the adapter 76 to create a passive sliding hemostatic seal against the shaft 97 of the catheter 95 without the necessity of tightening the threaded cap 87. Additionally, the adapter 76, in either embodiment, may have a tightly closed position for securing the catheter shaft 97 with respect to the patient. In other alternative embodiments, other known hemostasis valves may be substituted for the Tuohy-Borst adapter 76 as just described.

In a particularly preferred embodiment, the internal surface of the lumen 63 of the extension tube 62 and/or the internal surface of the lumen 57 of the body 51 are coated with a highly lubricious biocompatible coating, such as polyvinyl pyrrolidone, to ease the passage of the endoaortic occlusion catheter 95, and especially the occlusion balloon 96, through these lumens. Other commercially available lubricious biocompatible coatings can also be used, such as Photo-Link™ coating available from BSI Surface Modification Services of Eden Prairie, MN; sodium hyaluronate coating available from Biocoat of Fort Washington, PA; proprietary silicone coatings available from TUA of Sarasota, FL; and fluid silicone or silicon dispersions. Similarly, a distal portion of the exterior of the body 51 can be coated with one of these lubricious biocompatible coatings to facilitate insertion of the arterial bypass cannula 50 into the artery at the cannulation site. Furthermore, the endoaortic occlusion catheter 95 itself, in any of the embodiments described herein, can be coated with one of these lubricious biocompatible coatings to facilitate its insertion and passage through the arterial bypass cannula 50 and the patient's

vasculature. Preferably, the occlusion balloon 96 of the endoaortic occlusion catheter 95 should be free of any lubricious coating so that there is sufficient friction between the expanded occlusion balloon and the interior aortic wall to prevent accidental dislodgement or migration of the occlusion balloon 96.

In operation, the arterial bypass cannula 50 is prepared for insertion as shown in Fig. 1, with the tapered dilator 67 in place in the blood flow lumen 57 of the body 51 and with the fitting 76 completely closed. An arterial cutdown is made into an artery, preferably the patient's femoral artery, at the cannulation site or a guidewire is placed percutaneously using the Seldinger technique and the dilator 67 and the distal end 53 of the body 51 are inserted into the lumen of the artery with the bevel up. A suture 94 can be tied around the artery 93 where the body 51, as shown in Fig. 3, inserts to avoid bleeding from the artery 93 at the cannulation site. The dilator 67 is then withdrawn from the body 51, allowing blood to flash back and fill the lumen 57 of the body 51. When the tip 68 of the dilator 67 is proximal to the distal clamp site 56 an external clamp is applied to the distal clamp site 56 to stop further blood flow. The dilator 67 is completely withdrawn and the connector plug 71 is removed so that a tube 92 from the cardiopulmonary bypass system can be attached to the barbed connector 59 of the Y-fitting 58, as shown in Fig. 33. Air is bled from the arterial bypass cannula 50 by elevating the extension tube 62 and opening the fitting 76 slightly and releasing the external on the distal clamp site 56 to allow the blood to flow out through the fitting 76. Alternatively, air can be bled out of the arterial bypass cannula 50, through an optional vent fitting with a luer cap (not shown) that can be provided on the Y-fitting 58 or an infusion line and a three-way stopcock. The optional vent fitting can be also used as a port for monitoring perfusion pressure within the arterial bypass cannula 50. Once the air is bled out of the system, the external clamp can be removed from the distal clamp site 56 the cardiopulmonary bypass system pump can be turned on to

perfuse the patient's arterial system with oxygenated blood at a rate of about 3 to 6 liters/minute, preferably at a pump pressure of less than about 500 mm Hg.

To introduce the endoaortic occlusion catheter 95 into the arterial bypass cannula 50, an external clamp 91 is placed on the proximal clamp site 64, as shown in Fig. 3, to stop blood from flowing out through the extension tube 62 and the adapter 76 is opened all the way by unscrewing the threaded cap 87 to open up the passage 84 through the elastomeric seal 83. The distal end of the endoaortic occlusion catheter 95 with the occlusion balloon 96 mounted thereon is inserted through the passage 84 of the adapter 76 into the insertion chamber 66 of the arterial bypass cannula 50. Optionally, first and second depth markers 98, 99 may be printed on the shaft 97 of the endoaortic occlusion catheter 95 with a nontoxic, biocompatible ink. The first depth marker 98 on the catheter 95 indicates when the occlusion balloon 96 is entirely distal to the elastomeric seal 83. When the first depth marker 98 is positioned just proximal to the threaded cap 87, the adapter 76 should be tightened to create a sliding, hemostatic seal around the catheter shaft 97. Now, the clamp 91 can be removed to allow the catheter 95 to be advanced distally through the arterial bypass cannula 50.

Before the endoaortic occlusion catheter 95 enters the blood flow lumen 57 within the Y-fitting 58, the perfusion rate from the cardiopulmonary bypass system pump should be temporarily turned down to a rate of about 1 to 2 liters/minute to avoid hemolysis, tubing disruptions or other complications due to the additional flow resistance caused by the occlusion balloon 96 as it passes through the blood flow lumen 57. The catheter 95 can now be advanced distally until the occlusion balloon 96 is distal to the distal end 53 of the body 51. A second depth marker 99 on the catheter 95 indicates when the occlusion balloon 96 is entirely distal to the distal end 53 of the body 51. When the second depth marker 98 reaches the proximal end of the threaded cap 87, as shown in Fig. 3, the perfusion rate from the cardiopulmonary bypass system pump should be returned to a rate of about 3 to

6 liters/minute. The endoaortic occlusion catheter 95 can now be advanced into the ascending aorta for partitioning the heart and inducing cardioplegic arrest according to the methods described above. When the endoaortic occlusion catheter 95 is in position within the ascending aorta the adapter 76 can be tightened around the catheter 95 to act as a friction lock to hold the catheter in place.

After completion of the surgical procedure on the heart, the endoaortic occlusion catheter 95 can be removed from the cannula 50 by reversing the sequence of operations described above. The cannula 50 can remain in place until the patient has been weaned from cardiopulmonary bypass, then the cannula 50 can be removed and the arterial puncture site repaired.

It should be noted that for the venous side of the cardiopulmonary bypass system, a similar dual purpose venous bypass cannula and introducer sheath with the above-described features can be used for accessing the femoral vein and for introducing a venting catheter or other devices into the venous side of the circulatory system. In a venous configuration the dual purpose venous bypass cannula and introducer sheath preferably has an external diameter of about 21 to 32 French units, an internal diameter of about 18 to 30 French units, and a length of about 50 to 75 cm.

It should be noted that while several aspects of the present invention have been illustrated and discussed separately in the foregoing description, many of these aspects can be advantageously combined into a single, multifunction embodiment. As an illustrative example, Fig. 5 shows a multifunction embodiment of the endoaortic occlusion catheter 160 combining several of the inventive aspects previously discussed. As discussed above, however, any other aortic occlusion catheter may be used and preferred aortic occlusion catheters are described in U.S. Patent Application 08/692,992. The shaft 164 of the catheter 160 has a coaxial construction with an inner 161 and outer 162 tubular member. The shaft 164 may be made with varying degrees of stiffness along the length of the shaft 164, culminating in a soft atraumatic tip 165

which may be highly loaded with a radiopaque filler. The shaft 164 may be made with a precurved distal portion 166 or with a precurved distal portion 166 which is out of plane with the proximal portion of the shaft 164. An expandable occlusion balloon 163 is mounted on the distal portion 166 of the shaft 164. The balloon 163 preferably has a low profile deflated state with an ellipsoidal shape. In addition, the balloon 163 may have an eccentric or asymmetrical inflated profile 163' which would also provide a steering means for the distal tip of the catheter.

The occlusion balloon 163 is mounted with its distal balloon neck 167 attached to the inner tubular member 161 and its proximal balloon neck attached to the outer tubular member 162. The inner tubular member 161 is attached at its proximal end to a first hub 171 and the outer tubular member 162 is attached at its proximal end to a second 169 hub 171 which are axially slidably and/or rotatable with respect to one another. An infusion fitting 177, such as a luer lock, on the first hub 171 is connected to an infusion lumen 178 which terminates at the distal end of the catheter 160. An inflation fitting 170, preferably a luer lock, on the second hub 171 is connected to an inflation lumen 179 defined by an annular space between the inner 161 and outer 162 tubular members which communicates with the interior of the occlusion balloon 163.

The second hub 169 may be moved proximal and/or rotated with respect to the first hub 171 to minimize the deflated profile of the occlusion balloon 163. The lower deflated profile of the occlusion balloon 163 facilitates easy insertion of the catheter 160 through a dual function arterial cannula and introducer sheath 50. When the endoaortic occlusion catheter 160 is combined with the dual function arterial cannula and introducer sheath 50, the shaft 164 of the catheter 160 should be made with an additional 20-25 cm of length for a total shaft length of approximately 100-115 cm. The diameter of the catheter shaft 164 should also be minimized as much as possible to reduce the amount of cross sectional area the catheter shaft 164 takes up in the blood flow lumen of the arterial cannula 50. To this end, this

combined embodiment is made with a distal pressure transducer 172 and a balloon pressure monitoring transducer 173 mounted on the inner tubular member 161. The distal pressure transducer 172 and the balloon pressure monitoring transducer 173 are electrically connected to an electrical connector 174 on the first hub 171. Also on the first hub 171 is a fiberoptic connector 176 which connects to a fiberoptic bundle 175 which terminates with a means for directing a lateral beam of light at the distal end of the catheter 160 for aortic transillumination and/or for facilitating nonfluoroscopic placement of the catheter 160. The fiberoptic bundle 175 may also be made as a separate unit for insertion through the infusion lumen 178 of the catheter 160 to further reduce the catheter shaft diameter while maintaining maximum functionality. The diameter of the catheter shaft 164 can thus be reduced to as small as 8 to 10.5 French (2.7-3.5 mm diameter).

Referring to Fig. 6, a cross-sectional view of another preferred cannula 201 is shown. A specific application of the present invention is for arterial and venous cannulas for a cardiopulmonary bypass system. The methods and devices described herein in connection with arresting a patient's heart and placing the patient on cardiopulmonary bypass are incorporated here for use with the cannula 201 described below and any other cannula described herein. The cannula 201 includes a body 203 and a reinforced section 205. As will be discussed in greater detail below, the reinforced section 205 has a thin wall which maximizes the lumen size for a given outer diameter.

Referring to Fig. 7, an apparatus for forming the reinforced section 205 is shown. The reinforced section 205 of the cannula 201 is preferably manufactured with an elongate member 207 coated with a coating 209. The elongate member 207 may be made of any suitable material which has the requisite structural characteristics such as stainless steel, nickel titanium, or a polymer. A preferred material is 304V stainless steel wire having a 0.008 inch diameter. The

elongate member 207 may have any cross-sectional shape and a preferred shape is circular.

The elongate member 207 is preferably coated with the coating 209 by coextruding the elongate member and the coating 209. Any suitable coating 209 may be used and preferred coatings include polymers and specifically polyurethane, PVC, polyether block amide which can be purchased from Elf Atochem Inc. under the name **PEBAX**, and styrene block copolymer which can be purchased from Shell under the name **KRATON**. A preferred polyurethane is polytetramethylene glycol ether which can be purchased from Dow under the name **Dow 2363 PELLETHANE 80AE.**

The coating 209 is extruded over the elongate member 207 so that the coating 209 has opposing sides 211, 212 which are configured to engage one another when the coated elongate member 207 is wrapped around a mandrel 213. A preferred shape is a quadrangle, and specifically a square, however, any other shape may be used including irregular shapes so long as the opposing sides 211, 212 are configured to engage one another. The square cross-sectional shape preferably has sides having lengths between 0.010 and 0.020 inch and more preferably between 0.010 and 0.015 inch and most preferably 0.014 inch. The relative dimensions for the thickness of the cannula has been exaggerated as compared to the inner diameter for clarity with the actual dimensions being provided herein.

The coated elongate member 207 is wrapped around the mandrel 213 in a helical shape. The mandrel 213 is preferably coated with a lubricious coating such as TFE to prevent sticking. An advantage of the present invention over other methods of forming a cannula is that the coating 209 encasing the reinforcing member 207 does not have to flow between adjacent portions of the elongate member 207 since the elongate member 207 is coextruded to have a shape in which the opposing sides 211, 212 already engage one another. A shrink tube (not shown), preferably a heat shrink tube such as a polyester or fluorinated ethylene propylene (FEP) tube, may also be positioned around the elongate member 207 to facilitate bonding. The shrink tube is preferably removed

after heating. The wound coated elongate member 207 may also be dipped in a polymer solution such as polyurethane and tetrahydrofuran (solvent) to enhance the structural characteristics of the reinforced section 205. Furthermore, the coating or tube may also be applied over the wound coated elongate member. Alternatively, a tube may be positioned over the mandrel 213 and the coated elongate member 207 may be wound over the tube. The reinforced section 205 may be made of more than one layer of the coated elongate member 207 and the coated elongate member 207 may be wrapped in different directions to increase the hoop and tensile strength. Although it is preferred that the elongate member 207 has a constant cross-sectional profile, the elongate member 207 may also have differing sizes to provide stiff and flexible areas.

After the coated elongate member 207 has been wrapped around the mandrel 213, the coated elongate member 207 is heated to melt the coating 209 and fuse adjacent portions of the coating 209 together to form an integrated structure. The coated elongate member 207 is preferably heated using an oven, however, any other heating method may be used including an IR lamp, heating the mandrel 213, or a combination thereof. The coated elongate member 207 is then cooled and removed from the mandrel 213 thereby forming the reinforced section 205 of the cannula 201.

Referring to Fig. 8, the resulting reinforced section 205 is shown. The coating 209 on the elongate member 207 fuses together so that the coating 209 forms a matrix which is reinforced by the elongate member 207. Although it is preferred to heat the coated elongate member 207 to fuse the material together, the coated elongate member may also be coated with a solvent before winding the coated elongate member around the mandrel. The solvent would fuse the adjacent material together and would flash off leaving the fused material.

Referring again to the cross-section of Fig. 6, the reinforced section 205 has a lumen 215 therethrough for delivering or withdrawing fluids from a patient. The reinforced section 205 is attached to the body 203 by any

method and is preferably bonded to the body 203 by insert molding. The body 203 includes a lumen 217 which is fluidly coupled to the lumen 215 of the reinforced section 205. The body 203 has been simplified and may include valves, a Y-connection, luer connections or any other features. Furthermore, the body 203 is preferably configured to engage a 3/8 inch fitting which is a standard size for cardiopulmonary bypass systems. The lumen 215 of the reinforced section 205 may be any size but preferably has an internal diameter of at least 0.180 and more preferably at least 0.236 and most preferably at least 0.242 but no more than 0.375 inch.

A distal end 219 of the cannula 201 has an atraumatic tip 221 for introduction into the patient. The atraumatic tip 221 is preferably an integral extension of the coating 209 (see Fig. 8) extending beyond the reinforced section 205. The atraumatic tip 221 has a length of at least 0.050 and a thickness adjacent to the reinforced section which is preferably the same as the reinforced section.

A proximal end 223 of the reinforced section 205 is flared outward slightly so that the proximal end 223 has a larger lumen than the distal end 219. The proximal end 223 preferably forms an angle of between 2· and 10· and more preferably between 4·and 6· with respect to a longitudinal axis of the cannula 201.

The cannula 201 is particularly useful for arterial return and venous drainage cannulas for the cardiopulmonary bypass system described above since the cannula 201 can be manufactured with a thin wall. As such, the reinforced section 205 preferably has a thickness between 0.010 and 0.025 inch and more preferably between 0.013 and 0.020 inch and most preferably between 0.014 and 0.017 inch. The preferred thickness provides the necessary structural characteristics while maximizing the lumen size so that flow rates through the cannula are optimized. The cannula 201 of the present invention also has a unique spacing between adjacent portions of the coated elongate member. Referring to Fig. 8, a gap K between adjacent portions of the elongate member 207 is preferably less than 0.019 inch and more preferably less than

0.006 inch and most preferably less than 0.004 inch. A centerline spacing L between adjacent portions of the elongate member 207 is preferably less than 0.022 inch and more preferably less than 0.018 inch and most preferably less than 0.014 inch.

Referring to Fig. 9, a second preferred construction is shown for the reinforced section 205. The elongate member 207 and coating 209 are preferably the same as described above in connection with Figs. 7-8, however, another layer 225 is positioned either over the elongate member 207 or below the elongate member 207 to increase the strength of the reinforced section 205. When the layer 225 is on the radially inner wall of the cannula 201, the layer 225 may be applied by dipping the mandrel 213 in a suitable solution, extruding the layer over the mandrel 213 or positioning a tube over the mandrel 213. The coated elongate member 207 is then wrapped around the mandrel 213 and heated to fuse the coating 209 and layer 225 together. When the layer 225 is on the radially outer wall of the cannula, the layer 225 may be applied by dipping the coated elongate member 207 in a suitable solution after wrapping the coated elongate member 207 around the mandrel 213, extruding the layer 225 over the coated elongate member 207 wound around the mandrel 213, or positioning a tube over the coated elongate member wound around the mandrel 213 and fusing it to the coated elongate member. The coated elongate member 207 and coating 209 have the same preferred dimensions described above. The layer 225 has thickness of no more than 0.007 inch and more preferably between 0.001 and 0.003 inch and is preferably made of the same materials as the coating 209 described above. Fig. 9 depicts the reinforced section 205 before heating, however, after heating the polymer layer 225 and coating 209 fuse together to form an integrated structure.

Referring to Fig. 10, a third preferred construction for the reinforced section 205 is shown. The reinforced section 205 is made according to the same procedure described above except that a different elongate member 207A is used. The elongate member 207A is preferably made of metal and has a

quadrangle shaped cross-section. A preferred elongate member is a stainless steel flat wire having cross-sectional dimensions of 0.005 inch by 0.020 inch. The elongate member 207A is preferably coextruded with the coating 209 to a thickness of 0.003 all around although any thickness may be used. A layer 225A, which is preferably the same as the layer 225 described above, may be positioned on the radially inner or outer wall of the cannula. The resulting structure yields an inner diameter of at least 0.180 inch, more preferably at least 0.236 inch, and most preferably at least 0.242 inch and no more than 0..375 inch. The resulting reinforced section 205 has a thickness of 0.011 inch without the layer 225A and 0.013 inch with the layer 225A. The reinforced section 205 may also be formed without the layer 225A so that the wall thickness of the cannula is minimized. Fig. 10 depicts the reinforced section 205 before heating, however, after heating the layer 225A and coating 209 fuse together to form an integrated structure.

Referring to Fig. 11, a fourth preferred construction for the reinforced section 205 is shown. The reinforced section 205 is made according to the same procedure described above and has the same elongate member 207 as described in connection with Fig. 70. The coating 209B has an overlapping portion 227 which lies over an adjacent portion of the coated elongate member 207B. The elongate member 207B is a 0.005 inch by 0.020 inch stainless steel flat wire, and the coating has a width of 0.003 inch all around the elongate member 207. The overlapping portion 227 has a thickness of 0.005 inch and a length of 0.013 inch. The overlapping portion 227 provides an interlocking relationship between adjacent portions of the coated elongate member 207. Fig. 11 depicts the reinforced section 205 before heating, however, after heating the material from adjacent portions of the coating 209 and the overlapping portion 227 fuse together to form an integrated structure.

Referring to Fig. 12, a fifth preferred construction for the reinforced section 205 is shown. The fifth preferred construction differs from the first through fourth preferred

constructions in that the elongate member 207C is not coated before being wrapped around the mandrel. As discussed above, a known method of manufacturing reinforced tubing is to extrude a tube, mount the tube on a mandrel, wind a metal coil around the tube and position another tube over the coil. The tubes and coil are then heated so that the inner and outer tubes bond together. A problem with the known method is that relatively thick walled tubes are formed since the layers must be relatively thick to ensure sufficient strength since the wire must be spaced apart.

The elongate member 207C of Fig. 12 is made of a polymer, preferably 75D polyurethane, so that radially inner and outer polymer layers 229, 231 can fuse to the elongate member 207C to form an integrated structure. Thus, the polymer layers 229, 231 do not need to fuse together completely to form an integrated structure which overcomes a problem with prior art methods of forming reinforced cannulas. The polymer layers 229, 231, preferably 80A polyurethane, are positioned on opposite sides of the polymer elongate member 207C. The polymer layers 229, 231 are preferably softer than the polymer used for making the elongate member 207C. The elongate member 207C preferably has a diameter between 0.005-0.020 inch and more preferably between 0.008 and 0.012 inch. The layers 229, 231 preferably have a thickness of 0.002 to 0.015 inch and more preferably 0.005 to 0.10 inch. The elongate member 207C is preferably wound so that adjacent portions of the elongate member 207C contact one another, however, the polymer elongate member 207C may be wound so that a space exists between adjacent portions of the elongate member 207C. Furthermore, although the elongate member 207C preferably has a circular cross-sectional shape the elongate member 207C may have any other shape. The polymer layers 229, 231 may be applied in any manner including coextrusion, dipping or by simply using pre-formed tubes.

The polymer layers 229, 231 are preferably heated so that they bond with the elongate member 207C. The polymer layers 229, 231 are preferably positioned on both sides of the elongate member 207C before heating the layers 229, 231,

however, the layers 229, 231 may also be applied one at a time. By constructing the reinforced section 205 in this manner, the polymer does not need to flow completely between each part of the elongate member 207C to provide an integrated structure since the layers 229, 231 must simply bond to the elongate member 207C rather than having to bond with the opposing layer 229, 231. Fig. 12 depicts the reinforced section 205 before heating, however, after heating the polymer material from the layer 225A and coating 209 fuse together to form an integrated structure.

Referring to Fig. 13, a sixth preferred construction for the reinforced section 205 is shown with polymer and metal elongate members 207D, 207E wound together. Two polymer layers 229D, 231D are positioned on opposite sides of the elongate members 207D, 207E and may be provided in any manner described above. The polymer layers 229D, 231D are preferably softer than the polymer elongate member 207D. A preferred material for the polymer layers 229D, 231D is 75D polyurethane and a preferred material for the polymer elongate member 207D is 80A polyurethane. The soft polymer layers 229D, 231D are melted to bond to the polymer elongate member 207D thereby forming an integrated structure. The metal elongate member 207E provides structural strength and is preferably a stainless steel wire although any metal may be used. Although it is preferred that the elongate members 207D, 207E have circular cross-sectional shapes, the elongate members may have any other shape. Furthermore, although it is preferred that the elongate members have the same cross-sectional shape, the elongate members may also have different cross-sectional shapes. Fig. 13 depicts the reinforced section 205 before heating, however, after heating the material from the layers 229D, 231D and the elongate member 207D will fuse together to form an integrated structure.

Referring to Fig. 14, a seventh preferred construction for the reinforced section 205 is shown. A polymer elongate member 207F is wound together with a flat elongate member 207G. The polymer material for the polymer elongate member 207F may be any polymer and is preferably 75D

polyurethane. The flat elongate member 207G is preferably the same as the elongate member 207A described above in connection with Fig. 10. Two layers of polymer 229F, 231F encase the polymer and flat wire elongate members 207F, 207G. The polymer layers 229F, 231F are preferably softer than the polymer material of the elongate member 207F. The polymer layers 229F, 231F are preferably 80A polyurethane, however, any polymer may be used. The polymer layers 229F, 231F may be applied in any manner described above. The polymer layers 229F, 231F preferably have a thickness between 0.002 and 0.010 inch and more preferably between 0.004 and 0.008 inch. The polymer layers 229F, 231F are heated to bond to the polymer elongate member 207. Fig. 13 depicts the reinforced section 205 before heating, however, after heating the layers 229F, 231F and elongate member 207F fuse together to form an integrated structure.

Referring to Fig. 15, an eighth preferred construction for the reinforced section 205 is shown. A first elongate member 207H is preferably the same as the elongate member 207A described above in connection with Fig. 10. A second elongate member 207J is made of a polymer and has a thickness between 0.003 and 0.008 inch and more preferably 0.005 inch. Two polymer layers 229H, 231H encase the elongate members. The layers 229H, 231H are preferably 80A polyurethane having a thickness between 0.002 and 0.010 inch and more preferably between 0.004 and 0.008 inch. The polymer layers 229H, 231H may be applied in any manner described above. The polymer layers 229H, 231H are heated to bond to the second elongate member 207J.

Referring to Fig. 16, a ninth preferred construction for the reinforced section 205 is shown. A first elongate member 207L is wound around a mandrel 213 (not shown). The first elongate member 207L is preferably made of polymer, preferably 80A polyurethane, and has a T-shaped cross-sectional shape. The T-shaped cross-sectional shape has a width of 0.028 inch and a height of 0.008 inch. The first elongate member 207L has a radial extension 233 having a width of 0.008 inch. A second elongate member 207M, which is

preferably the same as the elongate member 207A described above in connection with Figs. 70, is wound over the first elongate member 207L. A polymer layer 229L is then positioned over the first and second elongate members 207L, 207M and is preferably 80A polyurethane having a thickness of 0.008 inch. The polymer layer 229L may be applied in any manner described above. The polymer layer 229L is then heated so that the polymer layer 229L and the radial extension 233 bond to one another to form an integrated structure.

Referring to Fig. 17, another preferred cannula 301 is shown. The cannula 301 is preferably used as the arterial return cannula for the CPB system described above. The cannula 301 includes the reinforced section 205 as described above. A tube 303 connects the reinforced section 205 to a Y-connector 305 which has first, second and third connections 307, 309, 311. The tube 303 is preferably a flexible tube made of estane 58810 42D polyether polyurethane. When using the cannula 301 for the CPB system described above, the first connection 307 is coupled to a source of oxygenated blood (not shown) while the second connection 309 receives an aortic occlusion catheter (not shown). The aortic occlusion catheter is used to occlude the ascending aorta and deliver cardioplegic fluid for arresting the patient's heart. The second connection 309 preferably receives the extension tube 62 and hemostasis valve 876 for receiving the aortic occlusion catheter in the manner described above in connection with Figs. 1-4.

A dilator 313 is used to facilitate introduction of the cannula 301 into the patient's artery. A dilator seal 315 seals the space between the cannula 301 and dilator 313. The dilator seal 315 and dilator 313 are removed after the cannula 301 has been introduced into the patient. Referring to Fig. 20, the end of the dilator 313 has an enlarged end 319 which engages an interior wall of the reinforced section 205 when passing through the cannula 301. The enlarged end 319 is preferred so that the dilator 313 does not contact the cannula 301 throughout the length of the dilator 313 thereby reducing

the resistance to moving the dilator 313 through the cannula 301.

Referring to Fig. 18, the method of forming the reinforced section 205 is shown. The reinforced section 205 has an elongate member 207N coated with a coating 209N with the elongate member 207N and coating 209N being any of the members 207A-M and coatings 209A-M described above in connection with Figs. 6-16. A preferred elongate member 207N is a 0.008 inch stainless steel wire which is coated with 80A durometer polyurethane to a 0.014 x 0.014 inch cross-section. The elongate member 207N is wrapped around a mandrel (not shown), as described above in connection with Figs. 6-16, and a soft tip 221N is butted against the elongate member 207N. The soft tip 221N preferably has the same thickness as the coated elongate member 207N with a preferred material being 90A polyurethane.

A layer 225N, which may be the layer 225 described above, is positioned over the coated elongate member 207N and the soft tip 221N. The layer 225N is preferably a tube having a thickness of 0.001-0.005 inch, more preferably about 0.003 inch, and is preferably made of the same material as the soft tip 221N. Although it is preferred to provide the layer 225N over the coated elongate member 207N it is understood that the layer 225N may also be positioned on the radially inner surface of the coated elongate member 207N (or not used at all). When the layer 225N is a tube, the tube has an inner diameter which is slightly smaller than the smallest outer diameter of the reinforced section 205. The tube is positioned over the reinforced section by inflating the tube, inserting the coated elongate member 207N into the tube, and deflating the tube so that the tube contracts around the helically wound coated elongated member 207N. By sizing the layer 225N somewhat smaller than the helically wound elongate member 207N, close contact between the layer 225N and elongate member 207N is ensured.

A heat shrink tube (not shown) is then positioned over the layer 225N, coated elongate member 207N, and soft tip 221N. The layer 225N, coated elongate member 207N and soft

tip 221N are then heated to fuse the material together to form an integral structure as shown in Fig. 19. The tip of the reinforced member 205 is then trimmed and a tapered mandrel is inserted into coated elongate member and a heat shrink tube is recovered over the tip to form a bevel 317 at an end 319 of the soft tip 221N which facilitates atraumatic insertion of the cannula 301. The end 319 is curved inward slightly to form a seal with the dilator 313.

The resulting reinforced section 205 preferably has an internal diameter of at least 0.180 inch, more preferably at least 0.200 inch, more preferably at least 0.236 and most preferably at least 0.242 but no more than 0.375 inch. The reinforced section 205 also preferably has a thickness of no more than 0.0020 inches, more preferably no more than 0.018 inches, and most preferably no more than 0.016 inch. When the coated elongate member 207N has a 0.014 x 0.014 inch exterior surface and the layer 225N has a 0.003 inch thickness the resulting thickness is about 0.0016 inch since about 0.001 inch is lost when the coated elongate member 207N and layer 225N are compressed with the shrink tube during heating. The unique combination of inner diameter and wall thickness provides an excellent cannula.

The methods and devices disclosed herein have been described in conjunction with cannulas, however, it is understood that the methods and apparatus may also be used for constructing any other hollow tubes including catheters and the like. While the above is a preferred description of the invention, various alternatives, modifications and equivalents may be used without departing from the scope of the invention. For example, the opposing sides of the coated elongate member 207 may have an S-shape, and the reinforced section 205 may have a varying wall thickness. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the claims.

WHAT IS CLAIMED IS:

1. A method of manufacturing a hollow tube, comprising the steps of:

coating an elongate member with a material thereby forming a coated elongate member;

winding the coated elongate member around a mandrel;

heating the coated elongate member after the winding step;

removing the coated elongate member from the mandrel.

2. The method of claim 1, further comprising the step of:

compressing the coated elongate member after the winding step and before the removing step.

3. The method of claim 1, wherein:

the coating step is carried out by coextruding the material over the elongate member.

4. The method of claim 1, wherein:

the coating step is carried out with the material being a substance selected from the group consisting of thermoplastics.

5. The method of claim 1, wherein:

the coating step is carried out with the material being a material selected from the group consisting of polyurethane, polyether block amide and PVC.

6. The method of claim 1, further comprising the step of:

dipping the mandrel in a solution after the winding step.

7. The method of claim 1, wherein:
the coating step is carried out so that the coated elongate member has a polygonal-shaped cross-section.

8. The method of claim 7, wherein:
the coextruding step is carried out so that the polygonal-shaped cross-section is a quadrangle

9. The method of claim 1, wherein:
the wrapping step is carried out with the mandrel having a circular cross-sectional shape.

10. The method of claim 9, wherein:
the wrapping step is carried out with the circular cross-sectional shape of the mandrel having a radius which varies along the longitudinal axis.

11. The method of claim 1, wherein:
the coating step is carried out with the elongate member being a metal wire.

12. The method of claim 1, wherein:
the heating step is carried out by heating the mandrel.

13. The method of claim 1, further comprising the step of:
positioning a layer on at least one of a radially inner and a radially outer side of the coated elongate member.

14. The method of claim 13, wherein:
the positioning step is carried out with the layer being a tube of material.

15. A cannula comprising:
a body having a first lumen; and
a reinforced section coupled to the body, the reinforced section having a second lumen fluidly coupled to

the first lumen thereby providing a fluid flow path, the reinforced section having a longitudinal length of at least 1 inch and a wall thickness of no more than 0.020 inch, the reinforced section having an elongate reinforcing member configured in a helical pattern and encased in a material, the second lumen having a diameter of at least 0.180 inch.

16. The cannula of claim 15, wherein:
the material encasing the elongate reinforcing member is a polymer.

17. The cannula of claim 15, wherein:
the reinforced section has a thickness of no more than 0.018 inch.

18. The cannula of claim 15, wherein:
the reinforced section has a thickness of no more than 0.008 inch.

19. The cannula of claim 15, wherein:
the second lumen has an inner diameter of at least 0.200 inch.

20. The cannula of claim 15, wherein:
the second lumen has an inner diameter of at least 0.236 inch.

21. The cannula of claim 15, wherein:
the body includes a third lumen fluidly coupled to the second lumen.

22. A cannula for delivering and/or withdrawing fluids from a patient, comprising:
a reinforced section having a first elongate member and a second elongate member, the first and second elongate members having helical shapes, the first and second elongate members being positioned side by side, the first and second

elongate members being encased in a material, the reinforced section having a first lumen; and

a body coupled to the reinforced section, the body having a second lumen fluidly coupled to the first lumen.

23. The cannula of claim 22, wherein:

the first elongate member is a made of a polymer and the second elongate member is made of metal.

24. The cannula of claim 22, wherein:

the reinforcing section includes a third elongate member, the third elongate member also being positioned side by side with the first and second elongate members.

25. The cannula of claim 22, wherein:

the first elongate member has a quadrangle cross-sectional shape.

26. The cannula of claim 22, wherein:

the second elongate member is made of a first polymer; and

the material encasing the first and second elongate members is a second polymer, the second polymer being softer than the first polymer.

27. A cannula for delivering and withdrawing fluids from a patient, comprising:

a reinforced section having an elongate member encased in a first polymer material, the elongate member having a helical shape and being made of a second polymer material, the reinforced section having a first lumen; and

a body having a second lumen fluidly coupled to the first lumen, the body being coupled to the reinforced section.

28. The cannula of claim 27, wherein:

the second polymer material is harder than the first polymer material.

29. The cannula of claim 27, wherein:

the elongate member has a circular cross-sectional shape and a diameter of between 0.008 and 0.012 inches, the first polymer material having a thickness of between 0.005 and 0.010 inches.

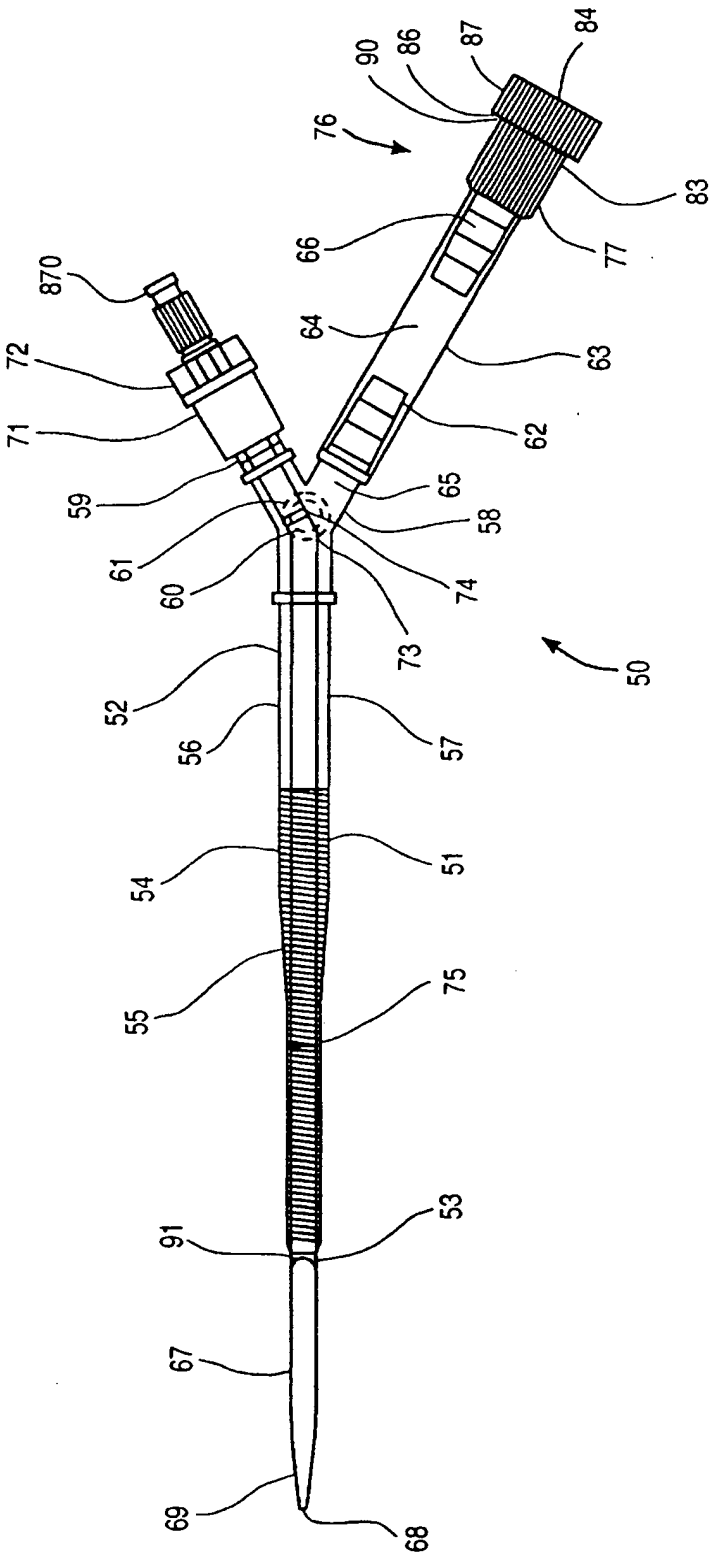
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FIG. 1

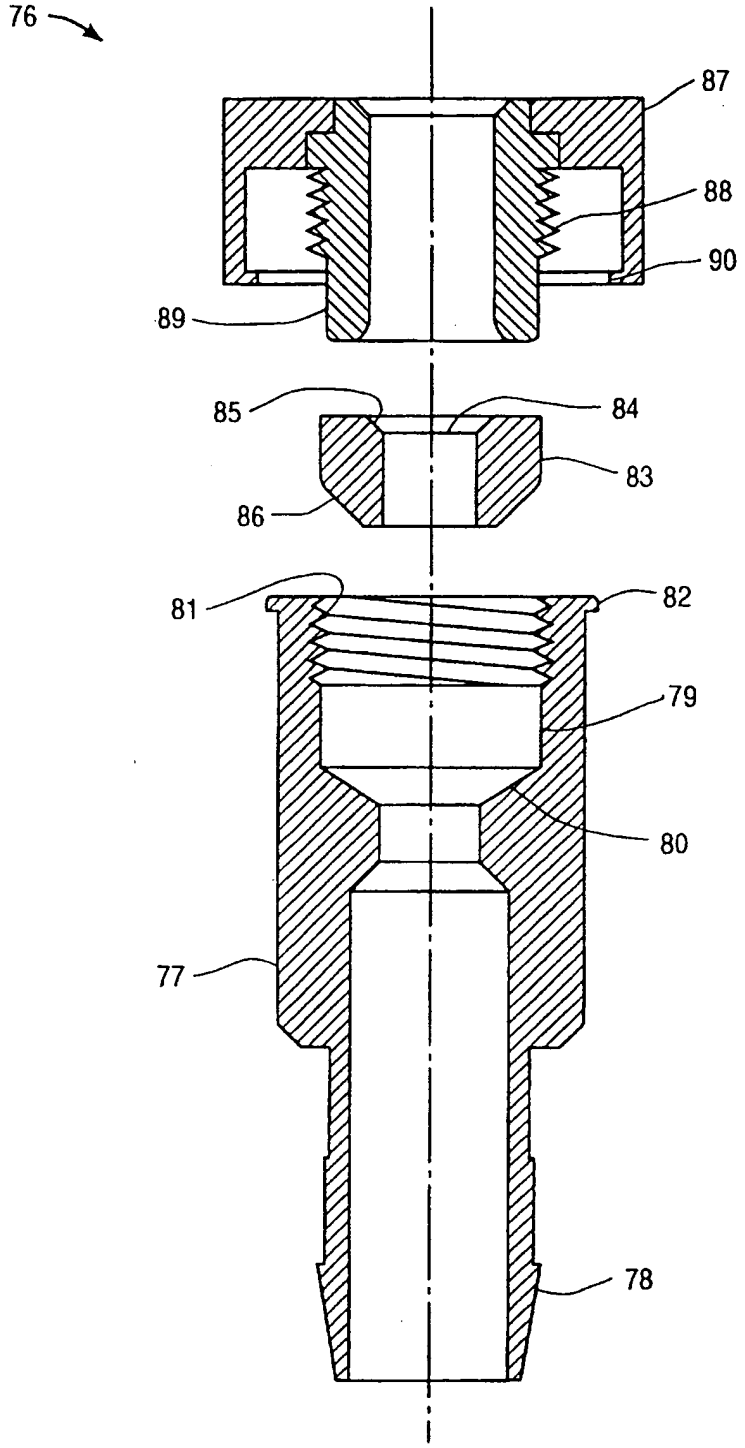

FIG. 2

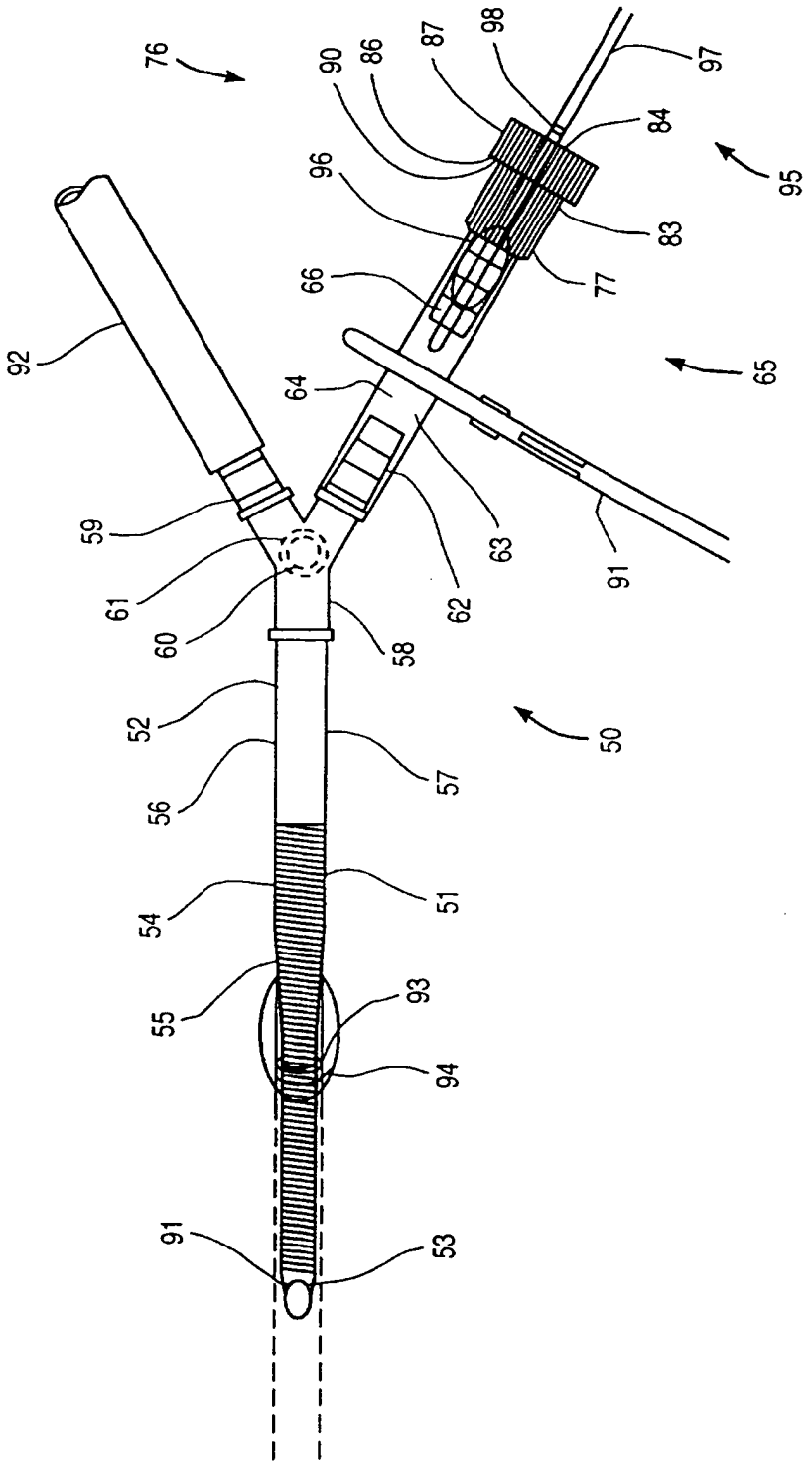
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FIG. 3

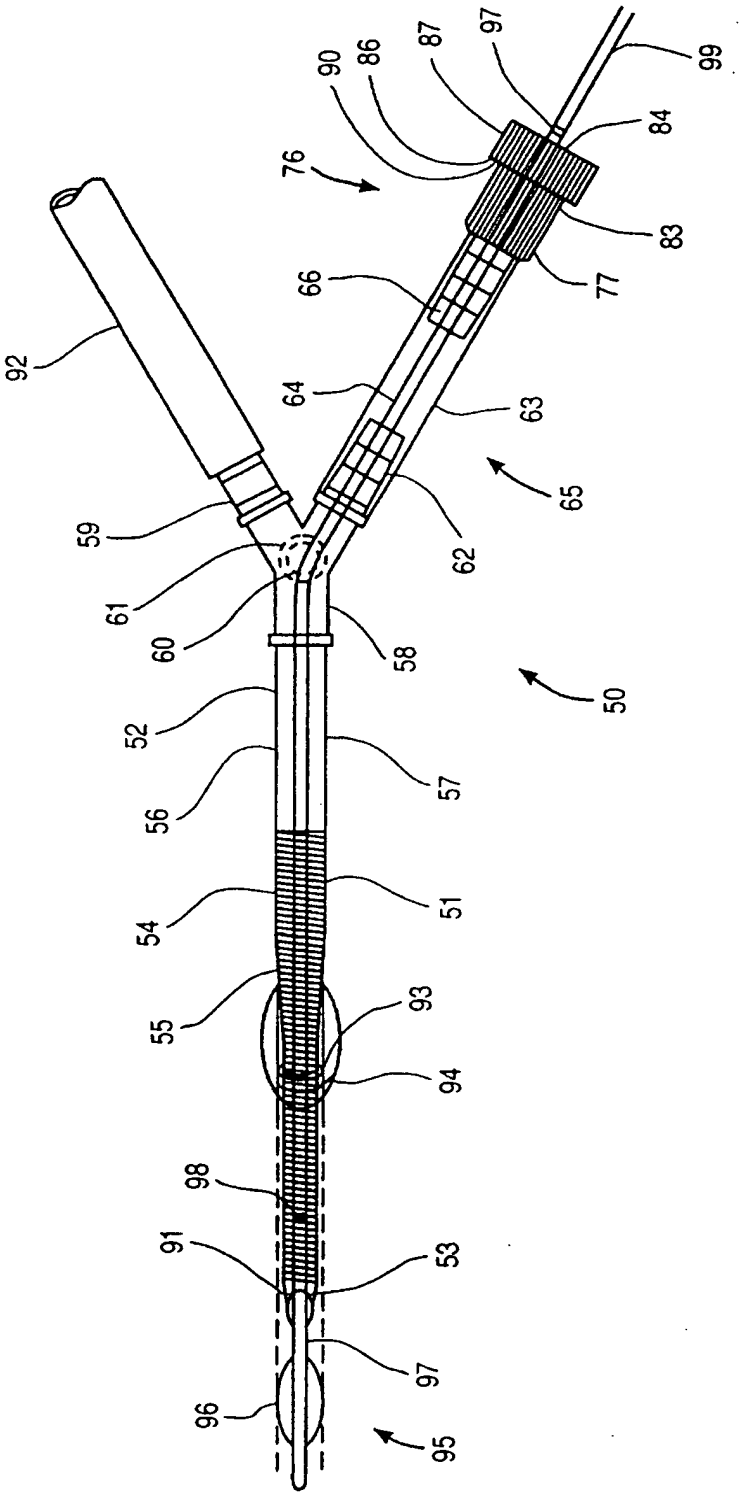
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FIG. 4

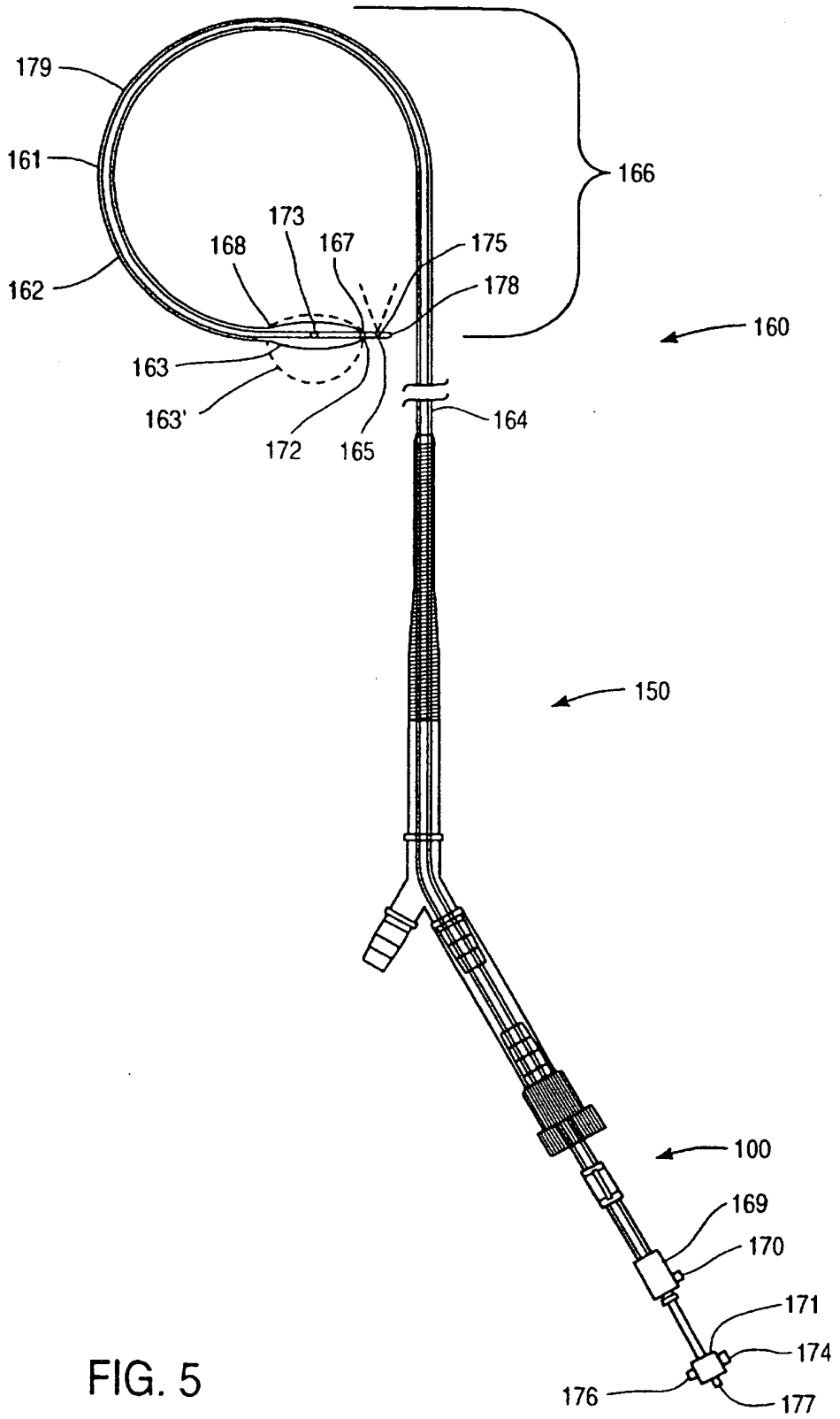
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FIG. 5

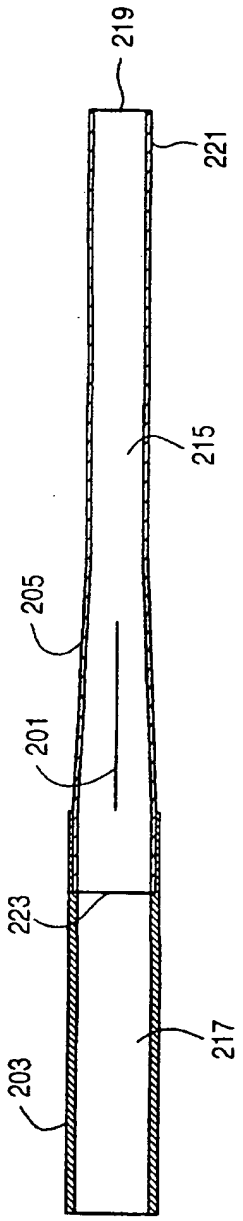


FIG. 6

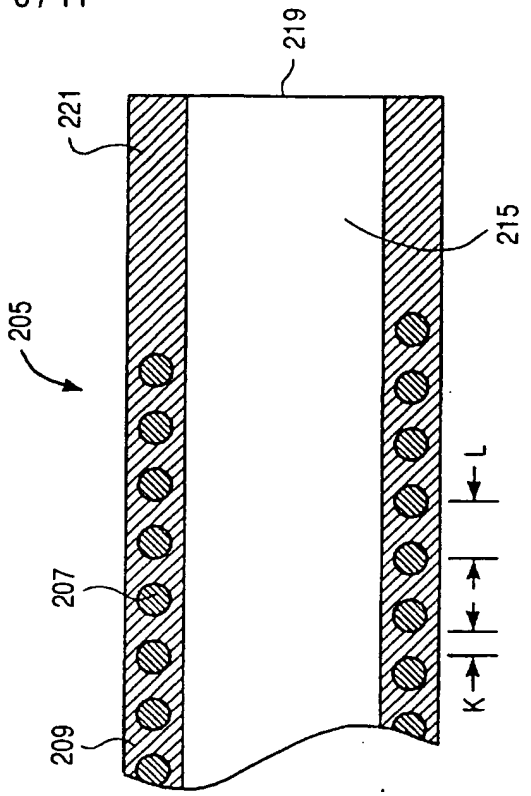


FIG. 8

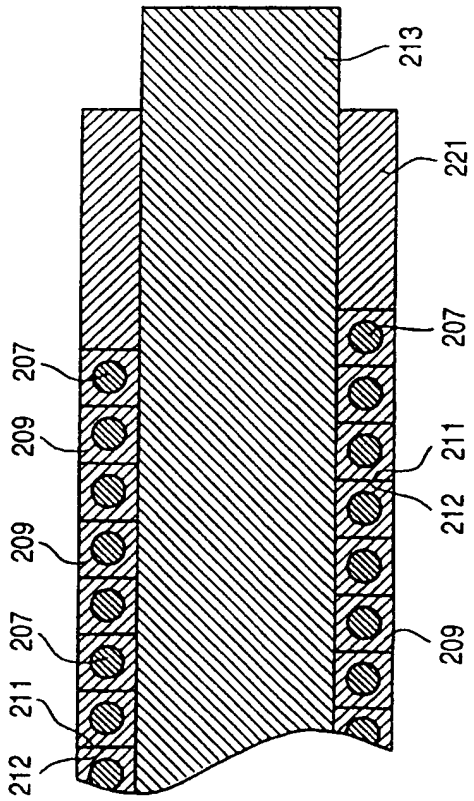


FIG. 7

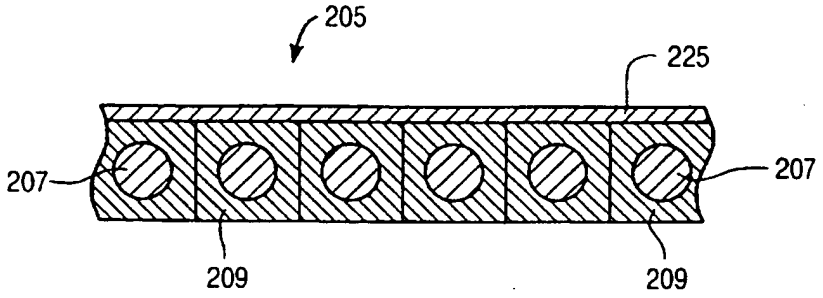


FIG. 9

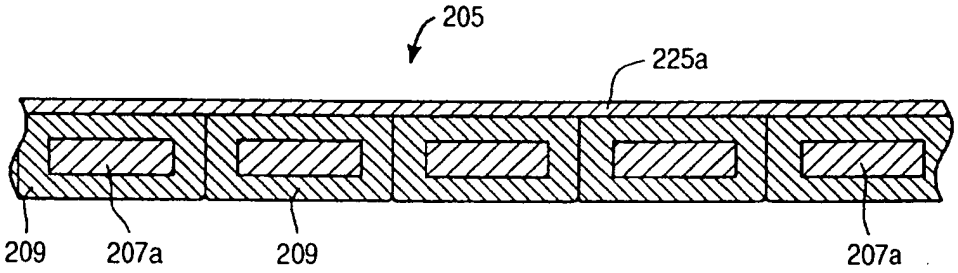


FIG. 10

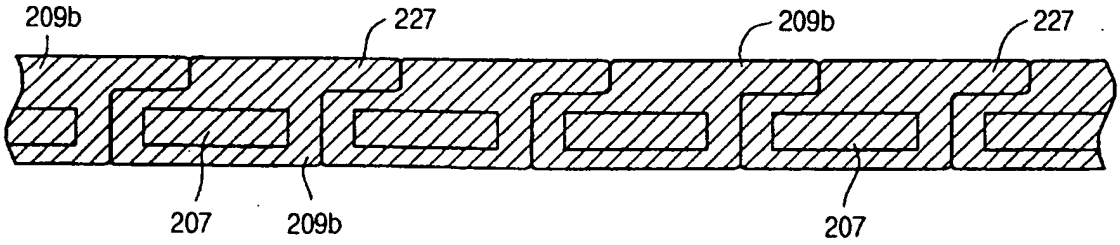


FIG. 11

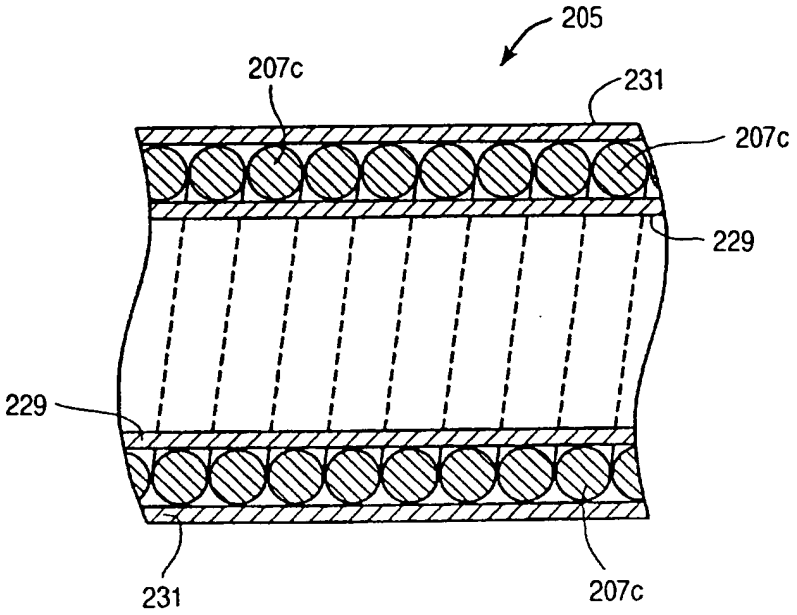
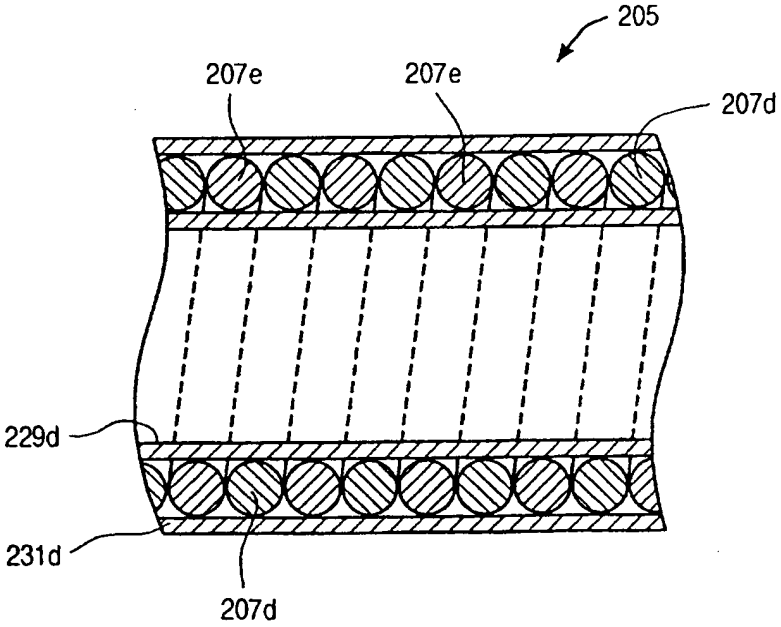

205
207c
231
207c
229
229
231
207c

FIG. 12


205
207e
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229d
231d
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FIG. 13

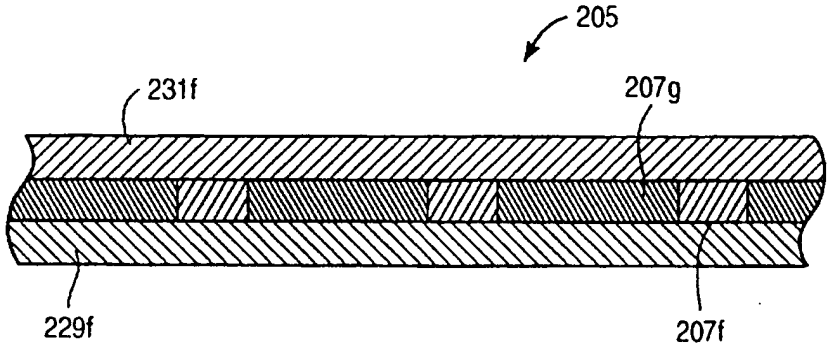

FIG. 14

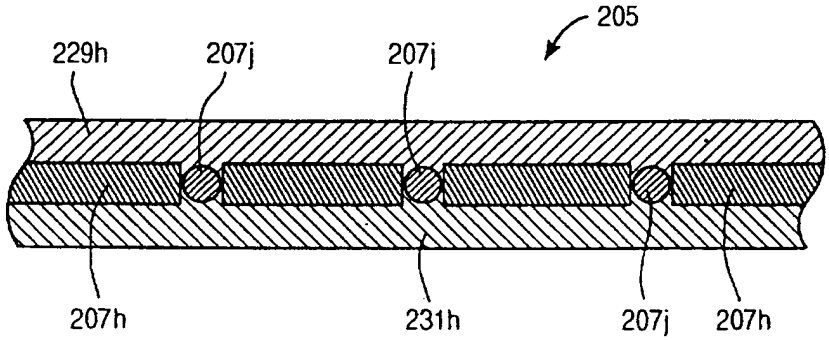

FIG. 15

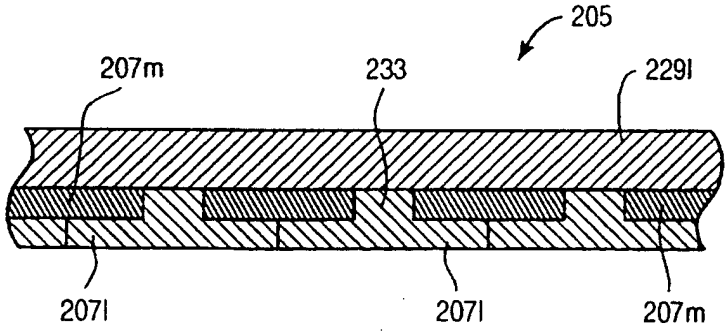

FIG. 16

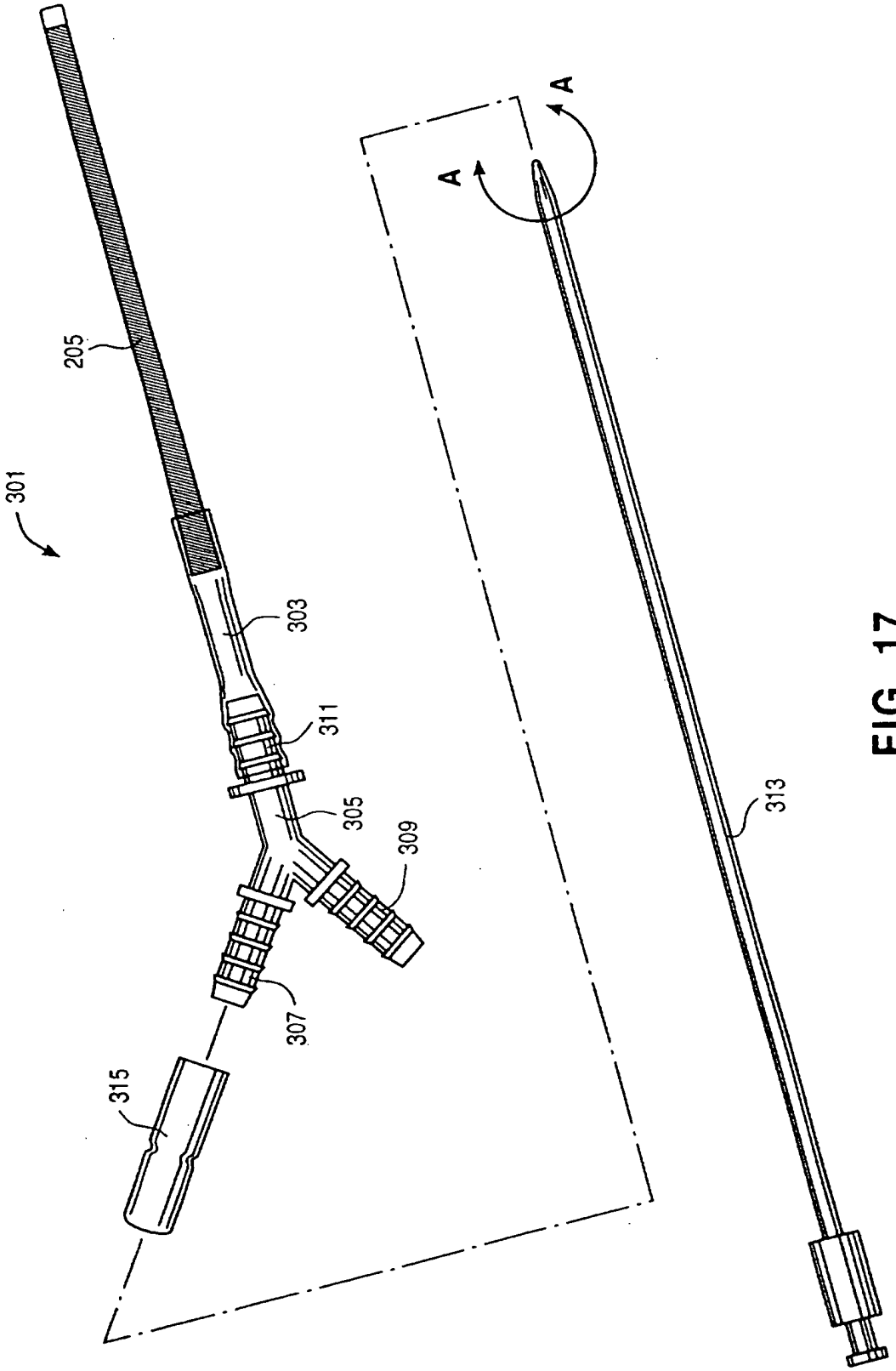

FIG. 17

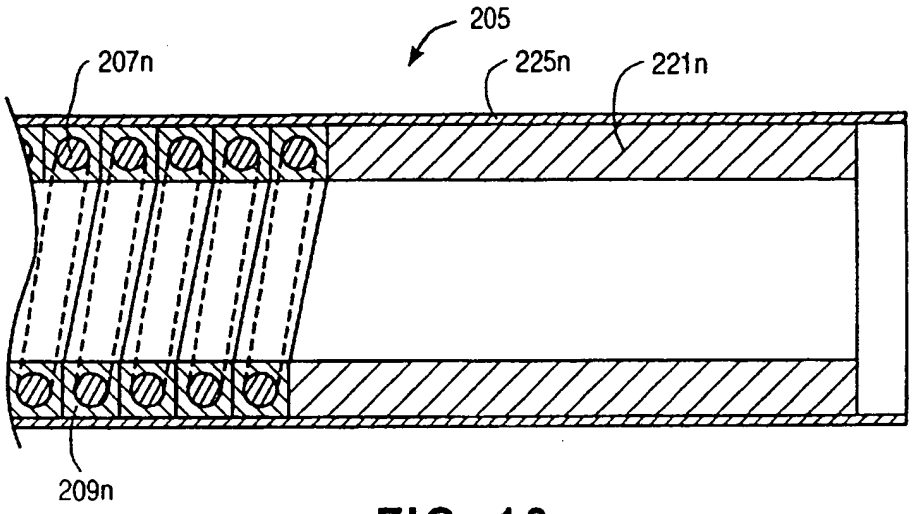

FIG. 18

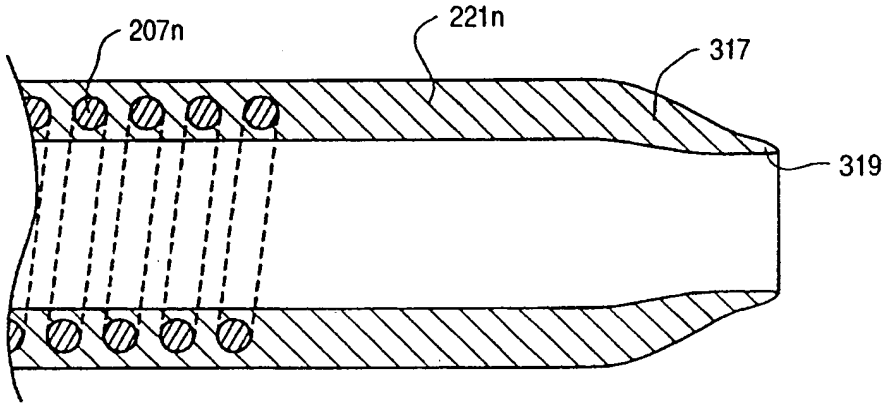

FIG. 19

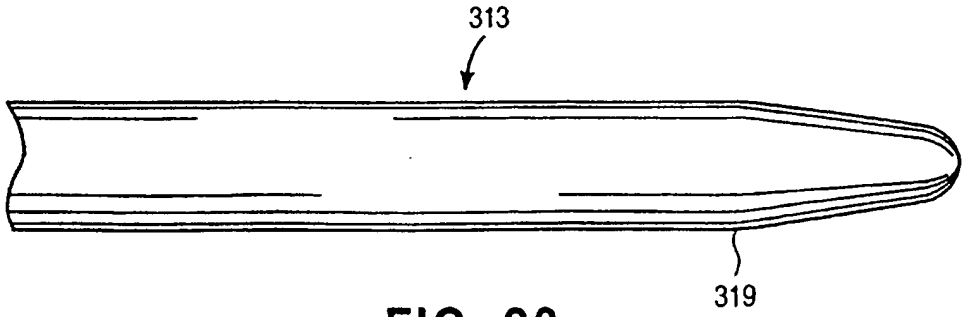

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/03543

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00
US CL :604/282

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 87/8.9; 138/118, 123, 129, 132, 172; 604/264, 280, 282

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS
Search Terms: tube, heat, mandrel, manufacture, braid, wind, reinforce

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, 4,842,590 A (TANABE et al) 27 June 1989, col. 4, lines 42-52; and Fig. 6.	15-17, 21, 22, 24 --- 23, 25-29
Y	US 5,176,660 A (TRUCKAI) 05 January 1993, col. 4, lines 1-4.	23, 25-29
A	US 4,899,787 A (OUCHI et al.) 13 February 1990, Abstract.	1-29
A,P	US 5,538,513 A (OKAJIMA et al) 23 July 1996, Abstract.	1-29
A,P	US 5,591,142 A (VAN ERP) 07 January 1997, Abstract.	1-29

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 25 APRIL 1997	Date of mailing of the international search report 12 MAY 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CORRINE M. MCDERMOTT Telephone No. (703) 308-2111

Form PCT/ISA/210 (second sheet)(July 1992)*